MINIMAL ACCESS SURGERY NEED SPECIFICATION DOCUMENTS: THE FILTERING PARAMETERS

The AIM (Affordable Inventions in Medical Technology) Fellowship Program

The Affordable Inventions in Medical Technology (AIM) Fellowship conducted by The Lemelson Foundation and InnAccel is focused on the creation and publication of a robust database of validated clinical needs within the Indian healthcare system based on hours of clinical immersion and extensive secondary research. In essence, it is meant to provide entrepreneurs, engineers, designers and others inclined toward healthcare innovation, with a solid foundation to build on as they create solutions to bridge key gaps and address specific unmet needs.

The Methodology: Following the Stanford BioDesign Process

The core essence of the BioDesign Process is the clinical immersion of multidisciplinary teams, to investigate and validate unmet clinical needs, identify gaps and opportunities in the need area, ideate and systematically select a lead concept to address the need, and determine its feasibility through prototyping and proof of concept testing. It consists of 3 phases Identify, Invent and Implement. Of these 3, this Fellowship was focussed only on the first.

The identify phase is, first and foremost, the search for important unmet health needs. By directly observing the full cycle of care from diagnosis and treatment to recovery and billing, we explore problems and opportunities and ask pointed questions that challenge the status quo. During this first-hand observation period, it's ideal to collect hundreds of needs, without judging or prioritizing. This is followed by filtering the list with rigorous objectivity. This intense and iterative process involves exploring epidemiology, criticality, technical complexity, competitor analysis and regulatory obstacles. Ultimately we narrowed down to 10 needs in each therapy area, which if solved would have a major impact on health and wellness.

This document details the 3 levels of filtering used during the AIM Fellowship to prioritise the top unmet needs

THE FILTERING PROCESS: 3 STAGES OF FILTERING

Level 1: The level 1 filter eliminated those needs which are redundant, pharmaceutical related or process related.

Level 2: This level of filtering focused on the severity of clinical condition (in the perception of observers and clinicians) as well as the epidemiology of the disease and the frequency of the negative outcome. This data was then validated by a comprehensive literature review of incidence and prevalence data. A scoring system of 1 – 3 – 5 was used through the process.

Epidemiology

Frequency of problem as per clinician (number of cases per month)

- < 5 patients per month=1
- 6-12 patients per month =3
- >13 patients per month =5

Frequency of problem as per observers (number of cases seen per month during the clinical immersion)

- < 2 patients per month=1
- 2-5 patients per month =3
- >5 patients per month =5

Criticality

- Short lasting, reversible: Not resulting in death, disability, hospitalization, or socioeconomic stress = 1
- Resulting in death, hospitalization >3 days, disability/ handicap (> 6 months), large financial burden to the patient/family = 5
- Needs in between 1 and 5 = 3.

Observed Epidemiology and criticality score: 3 (Frequency of clinician) + Frequency of observer + 3 (Criticality score)

Target patient population in a given year: We used data wherever available for India. However, in many cases due to the dearth of validated health statistics, certain assumptions had to be made using a combination of data from India and global epidemiological data.

- <100,000 patients/year = 1
- 100,000 – 500,000 patients/year = 3
- >500,000 patients/year =5

Secondary research based epidemiology and criticality score: Target patient population * Criticality score

Filter 2 score: Subjective epidemiology and criticality score + secondary research based epidemiology and criticality score

Level 3: The third level of filtering evaluated the technical complexity of the solutions available, the regulatory landscape and the buyer environment.

Number of predicates: This was made based on the solutions which currently exist as per guidelines and those being used in the Indian clinical setting. Both at prevailing practice as well as gold standards were considered.

- High number of predicates i.e. >5 = 1
- Medium number of predicates i.e. 1 to 5= 3
- No predicates = 5

Technical complexity of predicates: This filter considered the technology behind the solution as well as the expertise needed to implement it in current clinical practice. A medium complexity solution is rated the highest, followed by low complexity and lastly by a highly complex solution.

- High =1
- Medium =5
- Low =3

Regulatory and clinical trial complexity: This filter was based on the regulatory hurdles and clinical trials one would have to conduct for a particular solution. It was a judgment call based on the current predicates in the system and the classification of devices as per the Global Harmonisation Task Force classification (Class A - Low Risk, Class B - Low to Moderate Risk, Class C - Moderate to High Risk, Class D - High Risk)

- High (Class D) =1
- Medium (Class C) =3
- Low (Class A & B) =5

Buyer environment: This filter was based on the eventual buyer of a particular medical solution. This in turn depended on which level in the healthcare system the particular condition was treated. The peripheral immersion helped understand, more thoroughly, the referral system in India which defined this filter.

- High (Tertiary Care Centre) = 5
- Medium (Secondary Centre) = 3
- Low (Individual/Primary centre) = 1

Filter 3 score = Number of predicates score + Regulatory and clinical trial complexity score + Buyer environment score

Final Score= Filter 2 score + (Filter 3)/4

1. SURGICAL SITE INFECTION (SSI)

BACKGROUND

The skin is a natural barrier against infection. Even with many precautions and protocols to prevent infection in place, any surgery that causes a break in the skin can lead to an infection. Surgeons call these infections surgical site infections (SSIs) because they occur on the part of the body where the surgery took place.[1] If you have surgery in India, the chances of developing an SSI are about 4.2%.[2] An SSI typically occurs within 30 days after surgery. The CDC describes 3 types of surgical site infections: Superficial incisional SSI, Deep incisional SSI, Organ or space SSI. Any SSI may cause redness, delayed healing, fever, pain, tenderness, warmth, or swelling plus some specific symptoms based on the classification above. Infections after surgery are caused by certain microbial agents. The most common of these include the bacteria *Staphylococcus*, *Streptococcus*, and *Pseudomonas*. These bacteria can infect a surgical wound through various forms of contact, such as from the touch of a contaminated caregiver or surgical instrument, through germs in the air, or through germs that are already on or in your body and then spread into the wound. The degree of risk for an SSI is linked to the type of surgical wound you have. Surgical wounds can be classified in this way: Clean wounds, Clean-contaminated wounds, contaminated wounds, dirty wounds. These are other risk factors for SSIs such as surgery that lasts more than 2 hours, other medical problems or diseases, elderly patients, obesity, smoking, cancer, lowered immunity, diabetes, emergency surgery and certain specific surgeries such as abdominal surgeries. It is difficult to ignore the burden posed by surgical site infections (SSIs) on patients' safety in terms of pain, suffering, delayed wound healing, increased use of antibiotics and antibiotic resistance, revision surgery, increased length of hospital stay, mortality, morbidity and excess healthcare costs. SSIs have also been associated with the emergence of multi-drug resistant bacteria

OBSERVATION

A 25-year-old woman G3P2L2A1 underwent a laparoscopic vaginal hysterectomy for symptomatic fibroids in a tertiary health center. The patient was put in the lithotomy position, the abdomen was prepped and draped. A peri-umbilical incision was used to introduce pneumoperitoneum. A larger 10-12 mm trocar was placed above the umbilicus to provide a panoramic view of the pelvis. An 8-mm trocar was inserted in the lower quadrants, approximately 2-3 cm superior and 2-3 cm medial to the anterior superior iliac spine. In a bilateral fashion, the round ligaments were identified, grasped, and divided with bipolar or monopolar cautery, developing both the anterior and posterior leaf of the broad ligament. After ureteral identification, further retroperitoneal dissection allowed the ureter to fall laterally and away from active ligation and coagulation. A window was developed in the medial leaf of the broad ligament and the infundibulopelvic ligaments were sealed with suture, bipolar electrocautery, or surgical clips. Once the anterior and posterior colpotomies were opened, the uterine vessels were skeletonized, sealed, and divided with a sealing device or vessel clips. The remainder of the colpotomy was completed using monopolar or bipolar cautery. After the division of the uterus and cervix from the upper vagina, the specimens were then delivered through the vagina. The vaginal cuff was then closed with interrupted sutures. The patient was extubated and shifted to the post-operative room for monitoring and then to the ward. On postoperative day 3 she presented with fever, abdominal pain, and purulent vaginal discharge and was diagnosed with vaginal cuff infection post hysterectomy. She was re-admitted and started on IV antibiotics and had an abscess drainage in the hospital for an additional week before being discharged.

THE PROBLEM

Most SSIs are believed to be acquired during surgery. This is supported by the success of SSI prevention measures directed towards activities in the operating theater and a few reports demonstrating matching strains of pathogens from the surgeon's fingers and postoperative infection. However, despite much research on SSI, there are currently no data on the actual proportion acquired in the operating theater versus post-operative care in the wards. Similarly, within the subgroup of SSIs acquired during surgery, the proportion originating from the patient versus that transmitted by the surgical staff, operating theatre procedure or the environment remains unknown.[3] The risk of complications is poorly characterized in many parts of the world, but studies in industrialized countries have shown a perioperative rate of death from inpatient surgery of 0.4 to 0.8% and a rate of major complications of 3 to 17%. These rates are likely to be much higher in developing countries. Thus, surgical care and its attendant complications represent a substantial burden of disease worthy of attention from the public health community worldwide. Data suggest that at least half of all surgical complications are avoidable. SSIs remain a significant clinical problem as they are associated with substantial mortality and morbidity and impose severe demands on healthcare resources. The incidence of SSIs may be as high as 20%, depending on the surgical procedure, the surveillance criteria used, and the quality of data collection. [4, 5] Resultant increased hospital stay due to surgical site infection (SSI) has been estimated at 7-10 days, increasing hospitalization costs by 20%. [6]

NEED STATEMENT

An effective and definitive way to avoid infections at the post-op site in patients who have undergone open or laparoscopic surgical procedures in a tertiary healthcare setting.

FILTERING

Final score = 28

Rank = 1

MARKET POTENTIAL

Epidemiology: As per the 'Surgical site infection rates in 6 cities of India: Findings of the International Nosocomial Infection Control Consortium (INICC)', the SSI rates in India were: 4.3% for coronary bypass with chest and donor incision, 8.3% for breast surgery, 6.5% for cardiac surgery and 6.0% for exploratory abdominal surgery. [2]

Although the exact number of surgeries conducted in India is not available, a WHO report stated that countries spending US$100 or less per person on health care (of which India is a part,

spending $63 per capita per year) have an estimated mean rate of major surgery of 295 procedures per 100 000 population per year. This would equate to 3,835,000 procedures in a given year and reported incidence rates of SSIs ranging from 4.3% to 21% in some single-center studies. [2, 5]

COMPETITIVE LANDSCAPE

CURRENT PRACTICE

SSI precautions: The importance of peri-operative precautions have been established in various clinical trials and guidelines.

CURRENT METHODS OF SSI PREVENTION [1]

At present, four preventive measures are considered as having a high level of evidence (grade IA) according to major evidence-based guidelines: [3]

- **Surgical hand preparation**
- **Appropriate antibiotic prophylaxis**
- **Postponing of an elective operation in the case of active remote infection**
- **Hair clipping:** Pre-surgery hair clipping was considered grade IA evidence in the 1999 CDC guidelines this high grading is now a matter of debate.

Other measures of high efficacy include:[3]

- **Surgical expertise:** An excellent surgical technique is believed to reduce SSI by maintaining effective hemostasis while preserving adequate blood supply; gentle handling of tissue; removal of devitalized tissue; eradication of dead space; and appropriate management of the postoperative incision
- **Active Surveillance:** Decreases in SSI rates have been observed in national surveillance networks in countries, such as France, Germany, and The Netherlands. An active surveillance programme may decrease SSI rates by merely reporting data without any other formal interventions
- **Multi-Modal interventions:** Surgical checklists, quality care initiatives etc.

Widespread measures with low evidence: [3]

- **Wound closure:** Staples versus sutures are a hotly contested topic both are reported to be similar in terms of SSI risk. Some studies concluded that primary closure in dirty abdominal surgery leads to less SSIs than delayed primary closure, whereas others report the opposite.
- **Microbial sealing**: Mechanical blockage of pathogen migration to the surgical wound) may be a new approach to reduce wound contamination, but this has yet to prove its effectiveness in reducing SSI rates
- **Preoperative Bathing or Showering**
- **Preoperative Skin Preparation**
- **Gloves & Adhesive Drapes:** Sterile gloves and adhesive drapes are almost always used in the operating theater. They contribute to preventing site contamination and blood-borne

pathogen transmission from patients to surgeons. However, many gloves reveal tiny punctures after use that mostly go unnoticed and may double the SSI risk. Double-gloving or glove-changing might reduce the risk of punctures. A Cochrane review of 26 trials conducted on the practice of double gloving as a barrier precaution was inconclusive in terms of SSI reduction.

- **Laminar Airflow in the Operating Theater;** A retrospective analysis in Germany showed no reduction of SSI with laminar airflow versus no laminar airflow but needs to be corroborated with larger scale studies.
- **Oral Mechanical & Antibiotic Bowel Preparation:** A meta-analysis including 14 trials and 4859 patients failed to demonstrate a benefit of mechanical bowel preparation before colorectal surgery in terms of reduction of SSI or anastomotic leakage. The NICE guidelines do not recommend mechanical bowel preparation either.
- **Postsurgical Wound Care:** There is a paucity of literature on surgical wound care and SSI prevention. A Cochrane review assessed the effectiveness of various dressings and topical agents on surgical wound healing (and infection) and concluded that the quality of the trials was insufficient to determine any superiority of one protocol or one topical agent over another. Other randomized studies comparing occlusive versus gauze dressings equally failed to detect superiority in terms of SSI reduction or wound healing.

AVENUES OF RESEARCH IN SSI PREVENTION [1]

- Screening for MRSA Carriage on Admission
- Screening for Nasal *S. aureus* Colonization & Decolonization
- Avoidance of Intraoperative Hypothermia
- Avoidance of Intraoperative Hyperglycemia
- Supplemental Oxygen
- Naso- and oropharynx decontamination with chlorhexidine

MANAGEMENT OF SURGICAL SITE INFECTIONS

Culture: A tissue culture may be used to investigate the pathogen involved and thus tailor the antibiotic coverage

Symptomatic treatment: Management of shock, hypoventilation, and other complications should be provided

Antibiotics: Initial administration of empiric broad-spectrum antimicrobial therapy until the culture is obtained. Antibiotics with coverage against gram-positive and gram-negative organisms, including *Pseudomonas*, should be empirically started and then tailored according to susceptibility pattern of isolated organisms. Duration of therapy depends on several factors, including isolated pathogen, retention of a catheter, or the presence of complications (endocarditis, sepsis). For most bacterial organisms, the duration of therapy is 10-14 days after blood cultures become negative.

Surgical intervention: In cases such as abscesses, fistulas etc. antibiotics may not be sufficient to abate the infection and surgical intervention is needed as well.

EMERGING SOLUTIONS

Wound Protectors: Wound protectors are devices designed to protect the abdominal wound edges from contamination and trauma during laparotomy. They fall into 2 main design categories: those with an internal and external ring connected by impervious plastic and those with a single, internal ring connected to a drape that extends outward, over the wound edges and onto the abdomen where they are affixed with adhesive or clips. The reduction of SSI afforded by wound protectors is supported by several studies. However, other studies have obtained null results. [7]

207-nm Ultraviolet Light: A Promising Tool for Safe Low-Cost Reduction of Surgical Site Infections. Conventional germicidal UV lamps, typically emitting a broad spectrum of UVC light, are very effective at killing both bacteria and viruses. A particular advantage of UVC-mediated bacterial killing is that it is essentially independent of acquired drug resistance. [8]

Antimicrobial film drape: A novel preoperative antimicrobial silicone film drape designed to reduce the risk of bacterial contamination of the patient's skin prior to surgery by providing continuous antimicrobial activity. [9]

Specialised wound dressings and sutures: Wound dressing with nanofiber infused Vitamin D is a new technique recently published, as well as antimicrobial coated suture materials, are also available. [10, 11]

Operation Theatre Measures: Positive Pressure, exchanges of filtered air per hour, air-conditioning systems with HEPA filters, controlled airflow system (heating, ventilation, air-conditioning system: HVAC) and unidirectional-flow systems ("laminar airflow or LAF"). [12]

IDEAL SOLUTION STATEMENT

A solution that offers continuous inhibition of pathogen growth at the surgical site peri-operatively including during the follow-up period after discharge

NEED CRITERIA

MUST HAVE

- Continuous inhibition of pathogen growth
- Should be used both in-hospital as well as in the post-discharge follow-up period
- Should have no/minimal risk of contamination

- Should not be high skill from measurement or maintenance perspective

NICE TO HAVE

- Should be non-invasive
- Should be easy enough for an intensive care nurse to measure and maintain
- Should be portable

REFERENCES:

1. Surgical Site Infections: John Hopkins Health Library https://www.hopkinsmedicine.org/healthlibrary/conditions/surgical_care/surgical_site_infections_134,144
2. Surgical site infection rates in 6 cities of India: findings of the International Nosocomial Infection Control Consortium (INICC). International Health Advance Access published December 8, 2014
3. Uçkay, Ilker, et al. "Preventing surgical site infections." *Expert review of anti-infective therapy* 8.6 (2010): 657-670.
4. Owens, C. D., and K. Stoessel. "Surgical site infections: epidemiology, microbiology, and prevention." *Journal of Hospital Infection* 70 (2008): 3-10.
5. Setty, Naveen Kikkeri Hanumantha, et al. "A study on Surgical Site Infections (SSI) and associated factors in a government tertiary care teaching hospital in Mysore, Karnataka." *International Journal of Medicine and Public Health* 4.2 (2014).
6. Mahmoud NN, Turpin RS, Yang G, Saunders WB. Impact of surgical site infections on length of stay and costs in selected colorectal procedures. *Surg Infect (Larchmt)*. 2009 Dec. 10(6):539-44.
7. Edwards, Janet P., et al. "Wound protectors reduce surgical site infection: a meta-analysis of randomized controlled trials." *Annals of surgery* 256.1 (2012): 53-59.
8. Buonanno, Manuela, et al. "207-nm UV light—a promising tool for safe low-cost reduction of surgical site infections. II: In-vivo safety studies." *PloS one* 11.6 (2016): e0138418.
9. https://www.beckersasc.com/asc-quality-infection-control/antimicrobial-film-drape-receives-frost-sullivan-award-for-innovation-in-ssi-prevention-4-insights.html Accessed 10/8/2018
10. 1α,25-dihydroxyvitamin D3-eluting nanofibrous dressings induce endogenous antimicrobial peptide expression https://www.futuremedicine.com/doi/10.2217/nnm-2018-0011 Accessed 10/8/2018
11. Williams, Nia, et al. "Randomized trial of antimicrobial-coated sutures to prevent surgical site infection after breast cancer surgery." *Surgical infections* 12.6 (2011): 469-474.
12. Spagnolo, A. M., et al. "Operating theatre quality and prevention of surgical site infections." *Journal of preventive medicine and hygiene* 54.3 (2013): 131.

2. OPHTHALMIC COMPLICATIONS IN ENDOSCOPIC SINUS SURGERY

BACKGROUND

Chronic sinusitis is one of the more prevalent chronic illnesses across the globe, affecting persons of all age groups. It is an inflammatory process that involves the paranasal sinuses and persists for 12 weeks or longer. The literature has supported that chronic sinusitis is almost always accompanied by concurrent nasal airway inflammation and is often preceded by rhinitis symptoms; thus, the term chronic rhinosinusitis (CRS) has evolved to more accurately describe this condition. The overall prevalence of CRS in the has been said to occur in 1 in 7 individuals and for unknown reasons, the incidence of this disease appears to be increasing yearly. In the USA alone this results in approximately 18-22 million physician visits and a direct treatment cost of $3.4-5 billion annually.[1]

The first line of management for CRS is medical including antibiotics, anti-allergic drugs, nasal sprays etc. If the medical approach doesn't suffice, Functional Endoscopic Sinus Surgery (FESS) is the most appropriate surgical procedure for sinus pathology treatment. Over the last decade, the procedure developed to relatively safe. The overall incidence of minor and major complication after FESS is range from 0.4% to 30%. The anatomy proximity of the paranasal sinuses to the orbits exposes it is to the risk of trauma. The majority of orbital complications are minor ones (3.9–20.24%). The major complications are seen in 0.01–2.25%, but some of them could be serious, leading to permanent dysfunction and loss of vision. [2]

The ophthalmic complications could be classified as minor (grade I) included injury to the lamina papyracea, major (grade II) injury to the lacrimal duct and finally serious (grade III) as retroorbital hemorrhage, injury to the optic nerve or any reduction of vision or blindness and injury of orbital muscle. As the minor and major ophthalmic complications are normally without any permanent disabilities the serious ones are potentially harmful. [2]

OBSERVATION

A 42-year-old male was diagnosed with chronic rhinosinusitis (Bilateral frontals, maxillaries, and ethmoids) due to allergic hypersensitivity. Medical management was attempted and failed and he was scheduled to undergo FESS. The patient's nasal cavities were decongested following which the surgeon performed an uneventful procedure with endoscopic uncinectomy, maxillary antrostomy, ethmoidectomy and frontal sinus clearance. A day post-endoscopic sinus surgery he complained of a loss of visual acuity in the left eye. Immediately after surgery, no deficits in ocular motility were observed, but the left eye had no light perception. Acetazolamide IV and dexamethasone IV were given but his vision did not recover. The orbital CT revealed a hematoma around the left medial rectus muscle and a possible partial defect in the left optic nerve. The fundoscopic examination did not reveal any abnormalities. A visual evoked potential (VEP) test revealed an absence of left optic nerve activity. Orbital MRI showed resolution of the hematoma surrounding the left medial rectus muscle. The patient was treated with prednisolone orally for 10 days and then discharged. Orbital MRI was performed 2 months after

surgery. It revealed decreased contrast enhancement around the medial rectus muscle but a persisting fat line loss and a continued contrast enhancement behind the left optic nerve. Visual acuity remained zero.

THE PROBLEM

The incidence of ocular complications during ESS is rather low; they could be serious, leading to permanent dysfunction. The overall incidence of ESS complications are reported in several meta-analyses pointed its occurrence between 4.2–23% or 0.9–3.1%. There are only a few analysis of orbital complications during ESS. The incidence of this type of complications is range from 0.5% to 5%. However, due to the incidence of the disease and the high number of FESS procedures conducted year on year this number is quite significant. [2]

The orbit and its content are at risk during ESS because the lamina papyracea is very thin or may be incomplete. This site is the most potential risk area, especially when we do not have a good quality of vision or using powered instrumentation. The minor complications are referred to lamina papyracea injury mostly during maxillary antrostomy or ethmoidectomy. Complications are most common in patients with anatomical variations. These complications are commonly seen with hypoplastic maxillary sinus or Silent Sinus Syndrome (SSS). In this anatomic variants the uncinate very tightly connects to the lamina papyracea and should be resected with great attention. [2] The advent of the microdebrider was among the most important surgical instrument inventions in the field, advancing the treatment of sinonasal disease in a more visible field through its suction-based rotating blade however due to the thin lamina that patients are most at risk when the microdebrider can easily suction and sever periorbital and dura, which can then be misdirected into the orbit or brain [3]

The stages of surgery during which the orbit may be at the greatest risk of breach include ethmoidectomy or any ethmoid sinus surgery, and uncinectomy for the medial orbital wall, and maxillary antrostomy plus sinusotomy for the inferior orbit.

The risk factors for ophthalmic complications include: [2]

1. Surgeons skills and experience
2. Presence of Polyps
3. Higher Lund Mackay score (Severity of CRS)
4. Extension of the disease
5. Previous endoscopic surgery
6. Coexisting anticoagulant treatment.

NEED STATEMENT

A safer way to clear diseased tissue (soft tissue and bony tissue) in the sinuses to prevent major orbital complications such as nasolacrimal duct injury, retroorbital hematoma, optic nerve injury and one case of extraocular muscle injury.

FILTERING

Final score = 27.5

Rank = 2

MARKET POTENTIAL

Using the 1 in 7 chronic sinusitis prevalence, CRS would be seen in 134,000,000 in India. [4] Failure rate of medical management is approximately 50% in CRS = 67,000,000. Assuming all undergo FESS and the incidence of orbital complications in literature due to FESS ranges from 0.5–5%: Using 1%, that would equate to approximately 670,000 cases of ophthalmic complications a year regardless of severity and grade.

According to a market analysis report by Energias, the Global Sinusitis Treatment Market size is expected to reach USD 50.41 Billion in 2024, at a CAGR of 12.4% from 2018 to 2024. Factors propelling the growth of the market include a growing number of chronic sinusitis patients coupled with technological advancements in sinus surgery.

COMPETITIVE LANDSCAPE

CURRENT METHODS USED FOR PREVENTION OF OPHTHALMIC COMPLICATIONS

The risk of inadvertent orbital entry may be minimized by the following means: [5, 6]

- Good preoperative assessment
- Be wary of High-risk patients: Patients most at risk for complications include those with revision surgery, extensive disease, skull base anatomic or radiologic variations or dehiscences related to disease
- CT scanning: Assess the extent of the sinus disease and detect pre-existing anatomical variants.
- Both optic nerve and carotid artery form an indentation in the lateral wall of the sphenoid sinus. This can be unilateral or bilateral. 5%-7% of these have a dehiscent bone which exposes these two vital structures to the intraoperative injury. Preoperative imaging in the axial plane reveals excellent detail of the sphenoid sinus and its relationship with these two structures, thus avoiding iatrogenic complications.
- Thickness, contour, and presence of infraorbital or supraorbital structures should be identified.
- Early intraoperative location of the lamina papyracea provides a key landmark
- Special care must be exercised in using powered instrumentation

- The anterior ethmoidal artery is a critical structure to identify in order to avoid intra-operative bleeding. Coronal CT images show a bony nipple at the junction of the medial rectus and superior oblique muscles to identify a useful landmark for the location of this artery.
- Identification of sphenoethmoidal cells (Onodi), which occur in 8% to 14% of the general population before FESS is critical. Mistaking Onodi cells for the sphenoid sinus can lead to incomplete dissection and place the optic nerve and the orbit at risk.
- IV anesthesia, relative hypotension, and relative bradycardia minimize intraoperative blood loss.
- Topical decongestants, prothrombotic agents, and bipolar cautery should be available.
- Inspection of periorbita and periorbital fat if lamina papyracea is violated. If periorbita is not injured and there are no signs of orbital injury, surgery can proceed. If periorbita is cut, and orbital fat is exposed, intraocular pressure measurement and forced duction test should be performed.
- Blind cautery of the periorbital fat should be avoided to prevent injury to the EOMs and the ON. Bipolar electrocautery works well where bleeding does not involve the orbit itself.
- It is wise to keep the eyes uncovered during endoscopic surgery so that surgery can be stopped immediately if there is any indication of orbital swelling, afferent pupillary defect or eyelid bruising.
- Do not use nasal packing over the exposed orbital apex to avoid pressure on the ON.

MANAGEMENT OF OPHTHALMIC COMPLICATIONS

The complications often observed post FESS include: [6]

Orbital Hematoma: Orbital hematoma is an ophthalmic emergency because an intraorbital bleed can rapidly produce an orbital compartment syndrome (visual loss, external ophthalmoplegia, tense orbit, central retinal artery occlusion) with permanent injury to the optic nerve if ischemia persists more than 90 minutes. The source of bleeding may be injured lamina papyracea, periorbita, extraocular muscles, or traction on the orbital fat resulting in avulsion of an orbital vessel. Ligate the artery in question.

Diplopia: 15% to 63% of postoperative FESS patients report new onset diplopia or worsening of pre-existing symptoms of diplopia. Diplopia is due to change in the vector of pull of Extraocular muscles. Those who develop diplopia after decompression surgery often need strabismus surgery.

Epiphora: The incidence of this complication after FESS ranges from 0.3% to 1.7%. Endoscopic Dacryocystorhinostomy (EDCR) is the most commonly performed remedial surgery. Surgery on frontal sinus may damage lacrimal sac, whereas uncinectomy or middle meatal antrostomy may injure the nasolacrimal duct within the lacrimal canal.

Complications Related to Optic Nerve Sheath Decompression: This includes damage to the optic nerve fibers, ophthalmic artery, CSF leakage, meningitis etc. clear risks and absence of the data to suggest benefits of sheath decompression do not recommend this procedure in general.

Neuro-ophthalmic Complications: Anisocoria and accommodation palsy have been reported after endoscopic surgery. There is a favorable response to oral corticosteroids. Image aided neuro-ophthalmic procedures have made the procedure safer and improved the prognosis.

Optic Nerve Injury and FESS: Traumatic optic neuropathy may be direct or indirect. Direct traumatic optic neuropathy results from penetrating injuries where the intra-orbital portion of the optic nerve (ON) is generally injured. Indirect traumatic optic neuropathy is due to blunt head trauma with or without associated fractures of the orbital canal. The ON is at risk of injury within the sphenoid sinus, especially if there is a thin piece of bone or mucosa, separating the nerve from the sinus cavity. Maybe treated by decompression or steroid usage.

Extraocular Muscles (EOM) Complications: Detachment of the EOMs from the globe and their retraction into the posterior orbit can occur secondary to trauma or as a surgical complication. The muscle(s) may be ruptured or transected as a result of the injury. It is possible that a small defect in the orbital wall could allow a powered cutting instrument to aspirate orbital fat and or EOM into the sinus without entering the orbit. Loss of a rectus muscle may also occur as a complication of strabismus surgery, retinal detachment surgery, orbital surgery, or paranasal sinus surgery.

Orbital Abscess: Sinusitis continues to be the most common cause of orbital inflammation and infection, especially in children. May require orbital decompression.

RECENT ADVANCES IN ENDOSCOPIC SINUS SURGERY

Image-guided sinus surgery: Image-Guided surgery is a more detailed form of the FESS, which uses infrared signals and CT scans to get a more accurate picture of the sinus cavities in real time. This allows doctors to precisely target areas of concern while minimizing risk to arteries and other tissues that don't need to be removed. The advancements made in camera and telescopic technologies have allowed Image Guided surgery to become one of the most effective sinus surgery solutions on the market. [7]

Balloon Sinuplasty: This procedure offers patients the same sinus relief without any cutting or removal of sinus tissues. Instead, this method uses a small catheter and balloon that is inserted into the sinus cavity and inflated. As the balloon expands, it pushes the walls of the sinus cavity open and restructures them with a wider opening, without damaging the integrity of the lining of the sinus cavity. [7]

Medicated, dissolvable sinus stent: The PROPEL® sinus stent is another innovation intended to optimize recovery following endoscopic sinus surgery. Once the sinus is opened by the surgeon, the stent is inserted into the sinus that has been operated on, and it helps hold the sinus cavity open. As it does so, it also delivers anti-inflammatory medicine to the sinus tissue. The medicine is released for about 30 days. As the stent delivers drug it will dissolve over a 30 to 45 day period. The PROPEL sinus stent is proven to improve the outcomes of surgery by holding the sinuses open and treating the underlying inflammation. [8]

Three-dimensional endoscopic sinus surgery: The development of a miniature stereoscopic camera and its adaptation to rigid endoscopes allows for performance of 3D endoscopic sinus surgery. It is hypothesized that incorporation of 3D visualization may enhance the spatial resolution required in advanced endoscopic approaches with a theoretical potential to improve outcomes. [9]

IDEAL SOLUTION STATEMENT

An accurate, reliable and safe device that prevents the entry into the orbit and damage to periorbital structures while allowing the surgeon to dissect the sinus tissue and allow for complete clearance of diseased tissue during FESS.

NEED CRITERIA

MUST HAVE

- Must be accurate and precise in differentiating between diseased sinus tissue and orbital/periorbital tissue
- Must be reliable
- Must allow for complete clearance of diseased tissue
- Must not have a steep learning curve for otolaryngologists

NICE TO HAVE

- Must be affordable to all patients undergoing FESS
- Must be applicable in other similar procedures where an iatrogenic injury is possible
- Must be easy to use
- Must be portable enough to be shifted to different operation theatres

REFERENCES:

1. Rosenfeld, Richard M., et al. "Clinical practice guideline (update): adult sinusitis." *Otolaryngology–Head and Neck Surgery* 152.2_suppl (2015): S1-S39.
2. Seredyka-Burduk, Malgorzata, et al. "Ophthalmic complications of endoscopic sinus surgery." *Brazilian journal of otorhinolaryngology* 83.3 (2017): 318-323.
3. Chou, Tung-Wei, et al. "Multiple analyses of factors related to complications in endoscopic sinus surgery." *Journal of the Chinese Medical Association* 79.2 (2016): 88-92.
4. Comparison of Outcomes of Management of Chronic Rhinosinusitis by Conservative Approach Vs Endoscopic Sinus Surgery with Review of Literature. Dr Devendra M. Jain Journal of Medical Science and Research Volume 05 Issue 03 March 2017.
5. Rene, C., et al. "Major orbital complications of endoscopic sinus surgery." *British journal of ophthalmology* 85.5 (2001): 598-603.

6. Al-Mujaini, Abdullah, Upender Wali, and Mazin Alkhabori. "Functional endoscopic sinus surgery: indications and complications in the ophthalmic field." *Oman medical journal*24.2 (2009): 70.
7. https://www.americansinus.com/advancements-in-sinus-surgery-technology/ Accessed 27/8/2018
8. https://www.mysinusitis.com/propel/ Accessed 27/8/2018
9. Brown, Seth M., et al. "Three-dimensional endoscopic sinus surgery: feasibility and technical aspects." *Otolaryngology—Head and Neck Surgery* 138.3 (2008): 400-402.

3. PORT SITE HERNIA

BACKGROUND

Port site hernia (PSH) is a rare type of incisional hernia occurring at port sites after laparoscopic surgery. The incidence of PSH has an overall incidence of 1.7%. There are few prospective studies designed with the aim of identifying postoperative PSH. In these studies, the overall incidence was 3.2%. [1]

In large studies published prior to 1995 were identified, the incidence of PSH reported in each study 0.20%, 0.15%, and 0.13%, respectively which is considerably lower than more recent studies. The umbilicus is the most common port associated with incisional hernia, other sites include the epigastrium, the right hypochondrium, left hypochondrium. In the majority of cases, PSH is not associated with any strangulation or bowel obstruction. [1]

The incidence of port site hernia increases with the size of the trocar but there are other risk factors like the incision enlargement, infection, diabetes mellitus, obesity, the type of trocar used, male sex, connective tissue disorders and most importantly the defective closure of the fascial defect at the port site.[1]

OBSERVATION

A 40-year-old male presented to the emergency surgery ward with complaints of pain abdomen, distention abdomen, obstipation and two episodes of bilious vomiting for one day. The pain was diffusely present over the whole abdomen. On examination, tenderness was present in the whole abdomen with specific guarding present in the periumbilical area. There was a gurgling sensation just beneath the skin indicating the possibility of an obstructed gut loop which was found to be irreducible. He had undergone laparoscopic cholecystectomy two days before presentation and was discharged 24 hours prior. Ultrasonogram abdomen indicated only the dilated small bowel loops and abdominal radiographs revealed air-fluid levels in the erect film and grossly dilated bowel loops in the supine film. He was taken up for surgery and the abdomen was opened through the midline laparotomy incision extending a few centimeters above and below the umbilicus. The cherry colored gut loop was found lying just below the skin, herniating out of the peritoneal and the fascial defect at the umbilical port site. The loop was obstructed at the fascial defect. The defected fascia and the peritoneum were carefully opened and the loop was delivered out. Pregangrenous changes were present at the part of the loop stuck at the defect. The proximal bowel was grossly dilated while the distal bowel was somewhat collapsed. The obstructed area was approximately one foot from the ileocaecal junction. Approximately 500 to 600 ml of dark red edema fluid was also drained from the peritoneal cavity. The pregangrenous part of the ileum was kept under the warm saline soaked sponge and the patient was given 100% oxygen for full 5 minutes. The color and the peristalsis of the gut loop were rechecked and were found to have grossly improved. The small intestine was decompressed antegrade and retrograde, the wash was given and the abdomen was closed in layers with the proper anatomical repair of the fascia and the peritoneum. The patient

remained well in the postoperative period and the bowel sounds returned on the third postoperative day and the patient passed stools and flatus on the fourth postoperative day. The patient was allowed liquids on the third postoperative day and was discharged on full oral diet and treatment on the seventh postoperative day with a healthy stitch line.

THE PROBLEM

Very few prospective studies have aimed at identifying the risk factors for PSH. No randomized studies have been performed to date. The factors predisposing to PSH can be divided into patient factors and operative factors

Patient Factors [1]

- **Preexisting umbilical/paraumbilical hernia:** This has been identified in several reports as a risk factor for PSH in several studies
- **Preexisting umbilical or paraumbilical defects**
- **Male gender:** Males seem to have a higher incidence of hernias
- **Obesity:** Obesity has been suggested as a predisposing factor for PSH by some studies
- **Medical comorbidities**: Diabetes mellitus, COPD (chronic obstructive pulmonary disease), renal failure, AIDS

Operative Factors [1]

- **Trocar diameter**: This has been widely reported as a factor in the development of PSH
- **Port Insertion Technique:** Primary port insertion is either by a closed or open technique. Secondary ports are less often the site of hernia development, but hernias do occur at secondary port sites.
- **Type of trocar used:** The type of trocar used is thought to be a determining factor. They can be divided into cutting trocars and dilating trocars. The common cutting trocars are reusable metal pyramidal trocars and disposable metal bladed trocars with or without a sprung protective sleeve. They require less force to use but have a higher incidence of complications. Dilating or "radially expanding" trocars bluntly separate abdominal wall tissues and are thought to be associated with less bleeding and pain but require greater application of force. New hybrid designs have also been developed.
- **Port extension:** Case reports identify extension of the port incision especially to facilitate extraction of an organ such as the gallbladder as a risk factor for PSH
- **Wound infection**: Infections at the port site has been implicated in the pathogenesis of umbilical incisional hernia in some case reports
- **Insertion of a drain:** The use of a drain placed through a port site has been suggested as a risk factor for PSH in 2 studies, although this has not been fully evaluated.
- **Effects of Compressed Air.** Carbon dioxide might push the omentum or intestinal loops through the point of insertion in the fascia. The protruding structures might then be trapped by abdominal muscle contractions. [2]

NEED STATEMENT

An effective way to prevent the onset of port site hernia post abdominal laparoscopic surgery to prevent abdominal obstruction and other complications

FILTERING

Final score = 18

Rank = 3

MARKET POTENTIAL

Epidemiology: Assuming 18 million laparoscopic surgeries a year and using 1.7% incidence rate that would equate to approximately around 3,00,000 cases of port site hernia a year on average. Although the incidence is not high, the morbidity is significant both in terms of the additional laparotomy required for repair as well as the medico-legal implications for the healthcare provider. [7]

COMPETITIVE LANDSCAPE

CURRENT METHODS USED FOR PREVENTION OF PORT SITE HERNIA

Peri-operative improvement of health status: Martindale published an extensive review of perioperative interventions including smoking cessation, blood glucose control, and obesity. Smoking cessation for 4 weeks was found to be associated with a decrease in complication rate from 41% to 21% and Preoperative blood glucose control with hemoglobin A1c less than 7% and blood glucose between 140-160 mg/dL. [5]

Identify any previously undetected hernia: Conduct an examination of the fascia through the port site during surgery.

Careful suturing of the fascia of the umbilical port: Careful closure with sutures and where there is a preexisting hernia, formal repair should be undertaken with interrupted nonabsorbable sutures.

Use umbilical port as the extraction site: This minimizes the number of sites at increased risk of herniation.

Small Secondary ports: This port should be kept to as small in diameter as possible

Use of Dilating or hybrid ports: These port should be used in preference to cutting ports

Avoid reinsertion of ports and unnecessary torsion

Bioabsorbable Hernia Plug: New technology to prevent an incisional hernia in trocar sites implanted in the umbilical trocar site. [3]

Special closure devices: Consider using disposable suture retrieval needles and reusable blunt ligature guides. Some surgeons recommended the use of a fascial closure device, a spinal cord needle, a suture carrier, a 2-mm trocar or a Deschamps needle to close the fascia and the peritoneum together. [2]

Abdominal Deflations: Many authors have advised surgeons to open the trocar valve to deflate air before port removal so as not to draw omentum and intestines into the fascial defect. [2]

MANAGEMENT OF PORT SITE HERNIAS

Diagnosis:

- **Ultrasound and X-ray radiographs**
- **CT:** PSH of early-onset type can be located by computed tomography and surgically reduce and repair the hernia with minimal enlargement of the puncture wound, thus avoiding a full laparotomy. In many other reports computed tomography was available to diagnose early-onset–type hernias and were effective in diagnosing them. [2]
- **Gastrointestinal contrast study**: Found to be effective in 3 reports.[2]

Treatment

- **Non-operative management:** Nasogastric suction and other methods are said to often waste time and money, and they sometimes lead to critical conditions such as strangulation.
- **Laparotomy/Open surgery:** Depending on the bowel involvement the criticality and the procedure will vary: The bowel involvement can occur in the form of bowel incarceration, bowel obstruction or bowel evisceration. All these are considered surgical emergencies that can present a few days to weeks after the primary procedure.
- **Laparoscopic repair:** Recently, laparoscopic repair of trocar site hernias has been reported to be feasible [2]

IDEAL SOLUTION STATEMENT

A solution which prevents the development of port site hernia in an abdominal laparoscopic procedure that would prevent the herniation of bowel and/or omentum into the incision site leading to complications

NEED CRITERIA

MUST HAVE

- Must be safe to use

- Must not compromise surgical outcomes
- Must not itself lead to defects and hernias
- Must work at all port sites regardless of the diameter/extension

NICE TO HAVE

- Must be affordable
- Must be easy to administer

REFERENCES:

1. Bunting, David Mark. "Port-site hernia following laparoscopic cholecystectomy." *JSLS: Journal of the Society of Laparoendoscopic Surgeons* 14.4 (2010): 490.
2. Tonouchi H, Ohmori Y, Kobayashi M, Kusunoki M. Trocar Site Hernia. *Arch Surg.* 2004;139(11):1248–1256.
3. Moreno-Sanz, Carlos, et al. "Prevention of trocar site hernias: description of the safe port plug technique and preliminary results." *Surgical innovation* 15.2 (2008): 100-104.
4. Martindale RG, Deveney CW. Preoperative risk reduction: strategies to optimize outcomes. *Surg Clin North Am*. 2013;93:1041-1055.
5. Vorst, Alan L., et al. "Evolution and advances in laparoscopic ventral and incisional hernia repair." *World journal of gastrointestinal surgery* 7.11 (2015): 293.

4. ANASTOMOTIC LEAK

BACKGROUND

Intestinal anastomosis is a surgical procedure performed to establish communication between two formerly distant portions of the intestine. This procedure restores intestinal continuity after removal of a pathologic condition affecting the bowel. [1]

Indications for intestinal anastomosis can be broadly divided into two categories: restoration of bowel continuity following resection of diseased bowel and bypass of the unresectable diseased bowel. Certain pediatric conditions may also require intestinal anastomosis. [1]

Resection of diseased bowel is performed in the following settings: Bowel gangrene due to vascular compromise, Malignancy, Benign conditions (eg, intestinal polyps, intussusception), Infections (eg, tuberculosis), Traumatic perforations, Large perforations, Radiation enteritis, Inflammatory bowel disease, Chronic constipation, idiopathic slow transit constipation, or Hirschsprung disease. [1]

Bypass of unresectable diseased bowel is performed in following settings: Locally advanced tumor causing luminal obstruction, Metastatic disease-causing intestinal obstruction, Poor general condition or condition that prevents major resection [1]

Anastomotic leak (AL) is one of the most dreaded complications following colorectal surgery, with reported rates ranging from 3 to 26%. The concern over this complication is for good reason as it is associated with a mortality ranging from 6 to 39%. Many studies have looked at the potential causative factors of AL, and although male sex, poor nutritional status, obesity, and an increased number of blood transfusions may be risk factors, the level of the anastomosis is the most consistent risk factor for an AL. There appears to be an increased leak rate at the anastomotic site if done at or below 7 cm from the anal verge. [2]

Surgeons are all too familiar with the potentially devastating consequences of an anastomotic leak. Patients classically develop agonizing abdominal pain, tachycardia, high fevers, and a rigid abdomen, often accompanied by hemodynamic instability. In these cases, urgent return to the operating room for peritoneal washout and fecal diversion is generally required; prolonged stays in the intensive care unit and death are not uncommon. Further, anastomotic leakage has been associated with increased local recurrence and diminished survival after colorectal cancer surgery. [2]

However, a large number of patients ultimately found to have an anastomotic leak develop a more insidious presentation, often with low-grade fever, prolonged ileus, or failure to thrive. In these patients, making the diagnosis may be much more difficult as the clinical course is often similar to other postoperative infectious complications. Radiologic imaging is usually required; even then, the diagnosis may be elusive or at least uncertain. [3]

OBSERVATION

A 46-year-old male was scheduled to undergo a gastrojejunostomy due to severe peptic ulcer disease. The abdomen was entered using Veress needle insufflations. 4 to 5 trocars were placed in the upper abdomen under direct vision, with 1 to 2 of these trocars being 12mm in size and the rest being 5mm. After placement of trocars, the greater curvature of the stomach was identified. The gastrocolic omentum was opened using an ultrasonic or Harmonic scalpel. The lesser sac was entered, and the distal stomach was identified. The position on the distal stomach for the creation of the GJ was based on the surgeon's preference. A loop of small bowel approximately 30cm to 50cm distal to the ligament of Treitz was chosen for the gastrojejunostomy. A laparoscopic stay suture was used to align the small bowel segment in an antecolic manner to the anterior or posterior wall of the stomach. Enterotomies were then made with cautery in both the jejunum and stomach. 2 to 3 staplers were used to create the anastomosis. The common enterotomy was closed laparoscopically with 2 layers of sutures.

The patient had an anastomotic leak requiring open repair of GJ on postoperative day 5. This patient had an arduous postoperative course complicated by septic shock, respiratory failure necessitating a tracheostomy, and formation of an enterocutaneous fistula that was repaired 3 weeks later. She ultimately improved and was discharged to subacute rehabilitation 10 weeks after her initial surgery.

THE PROBLEM

Anastomotic leakage is the most feared early complication of intestinal anastomosis.

A great deal is known about the healing of the external skin after injury, but much less is known about intestinal healing. This is due to the easy accessibility of the skin as it heals as opposed to the intestinal mucosa. The gastrointestinal tract wall is composed of the surrounding serosa; the smooth muscle-containing muscularis propria; the collagen-containing submucosa providing tensile strength; and the epithelial mucosa and mucous layer that provide the interface with and the barrier to the luminal contents. Most importantly the intestinal mucosa heals in close contact with the intestinal microbiota, the densest biomass in the body. The healing of an intestinal anastomosis occurs in three phases: [1]

- Inflammatory phase
- Fibroplasia phase
- Remodeling phase

During the inflammatory phase, the integrity depends on the mechanical strength provided by sutures. The inflammatory phase is followed by the fibroplasia phase around postoperative days 5-7. Collagen deposition occurs in this phase, which gives strength to the anastomosis. Any systemic or local factor that causes a delay in the transition from the inflammatory phase to the fibroplasia phase can result in poor healing and anastomotic leakage.

Systemic conditions that increase the risk of anastomotic leakage include anemia, diabetes mellitus, malnutrition, hypoalbuminemia, vitamin deficiencies, and steroids. Local factors which affect healing include radiation, disease-affected bowel, and inadequate blood flow.

Anastomotic leakage presenting on postoperative day 1 or 2 is invariably due to technical reasons. Anastomotic leakage secondary to interference in the normal healing mechanism usually presents around the end of postoperative week 1. Anastomotic leakage can present either as frank peritonitis when the leak is uncontrolled or as localized intra-abdominal collection/abscess if the leak is controlled. A leak with diffuse peritonitis is associated with high morbidity and mortality and necessitates re-exploratory surgery.

NEED STATEMENT

A safer way to create an intestinal anastomosis in laparoscopic or open abdominal procedures to prevent anastomotic leak leading to complications such as septic shock, re-exploration surgery, and mortality

FILTERING

Final score = 18

Rank = 5

MARKET POTENTIAL

As was mentioned in the background section, the indications for intestinal resection and anastomosis are extensive. Unfortunately, data on the frequency of these procedures across the country is hard to come by but given the incidence of colorectal cancers, peptic ulcer disease in India these are not infrequent.

In the USA alone the number of colorectal procedures carried out per year is said to be 320,000 as per the report titled Trends in Operating Room Procedures in U.S. Hospitals, 2001–2011. If we assume that the proportion of procedures to population is constant that would entail that there are 12,80,000 colorectal procedures alone performed in India. Given the incidence of anastomotic leak that would entail a range of 3840 – 3,32,800 in colorectal procedures alone.

Given the poor surgical outcomes, repeat procedures, sepsis, and mortality risk this is certainly an important unmet need to be addressed.

COMPETITIVE LANDSCAPE

CURRENT METHODS USED FOR PREVENTION OF ANASTOMOTIC LEAK

The risk of inadvertent nerve trauma due to an accidental transaction or heat-related injury may be minimized by the following means:

Risk factors & Prediction: Extensive literature is available on the topic of risk factors for anastomotic leakage. These include male gender, smoking, obesity, alcohol abuse, preoperative steroid and non-steroidal anti-inflammatory drugs use, longer duration of operation, preoperative transfusion, contamination of the operative field and timing during duty hour. In a study of 452 consecutive patients undergoing bowel resection with anastomosis, Erb et al found that abnormal vital signs were common after surgery and did not accurately predict the presence of anastomotic leaks. In postoperative week 1, fever, tachycardia, tachypnea, hypotension, and leukocytosis occurred daily in approximately 70% of patients who did not have anastomotic leaks and in more than 90% of those who did. The positive predictive values for fever, hypotension, and tachypnea were 11%, 4%, and 4%, respectively. Recently, risk factor studies have also been undertaken for laparoscopic colorectal surgery, identifying body mass index, tumor distance from the anal verge, tumor depth, and pelvic outlet as independent predictors for increased operative time and morbidity after laparoscopic total mesorectal excision [4, 5]

Surgical technique: Although some prerequisites should be present as adequate blood flow, without any tension in the absence of peritonitis, no clear value can be given for these aspects. Although there is little supporting evidence an inverting single layer continuous suture technique with slowly absorbable monofilament material seems preferable. Strong evidence lacks for other important aspects as the distance from the suture to the edge of the anastomosis, the distance between the sutures, layers included in the suture, suture tension and the optimal configuration. With regards to stapling *vs* hand-sewn anastomosis in colorectal anastomosis these are found to be equally effective although stapling techniques might be of preference since the technique is uniform and easy to learn, making it ideal for comparing results between hospitals and surgeons and for teaching young surgeons. There is a need for the development of new techniques since all previous research has not lead to radically decreased leakage rates. [6]

Extra-luminal sealing using fibrin glue or acrylates: These agents are reported mostly in animal studies but the few reports on their use in human colorectal anastomosis have not shown beneficial effects on colorectal anastomosis. [6]

Endo-luminal sealing by means of a biodegradable barrier: This technique has shown to be successfully applied in humans and a multicentre randomized clinical trial is currently being undertaken. [6]

Leak Test: Intraoperative evaluation, is commonly performed following the creation of esophageal, gastric, and rectal anastomoses, where the anastomosis is proximal or distal enough in the bowel to be accessible by endoscopy. [7]

Diverting Ileostomy: In colorectal anastomoses, some surgeons perform a diverting ileostomy. This procedure and its subsequent reversal carry the independent risks of morbidity and add costs, the impact that diversion has on prevention of anastomotic leak remains unclear. The theory behind fecal diversion is that it eliminates the anastomotic stress of bowel wall dilation during healing and that any leakage that occurs has less severe consequences by avoiding large volume of fecal spillage. [7]

Trans-anal drainage tubes, Trans-anal sponge: The vacuum drainage developed for wound therapy, represent an alternative treatment for anterior rectal anastomotic leaks. The principle of this method is the application of negative pressure on the wound surface with the help of a sponge connected to a pump. The physiological mechanism of this improvement in wound healing is the effective removal of fluid, tissue edema and bacteria, with subsequently improved local blood circulation, which in turn stimulates wound healing (increased growth of granulation tissue). [8, 9]

Fat cell Harvesting: Cytori Therapeutics has developed a method of harvesting regenerative cells from subcutaneous fat. These cells, which include a high proportion of stem cells, can be used for a variety of applications, including wound healing and treating inflammation. [10]

MANAGEMENT OF ANASTOMOTIC LEAK

Early detection [6]

Clinical assessment: Anastomotic leakage becomes apparent between the 5th and the 8th postoperative day, but exceptions do exist. Clinical signs include those of systemic inflammatory response syndrome: fever, ileus, and pain are frequent. However as mentioned earlier but have low positive predictive value.

Risk scores: Clinical scoring systems such as the Dutch Leakage Score was shown to be useful in those patients with a higher score were prone to anastomotic leak and required intensive clinical observation or radiological evaluation. Scoring systems can reduce delays in diagnosis of anastomotic leak and decreases false negative diagnostic imaging representing a major factor of delay in diagnosis. Although it is not known if the application of the score leads to an increase of negative imaging, the score could be especially beneficial in daily clinical practice where young doctors and nursing staff could identify high-risk patients very easily and in a standardized manner. [6]

CRP based prediction: This interval between surgery and clinical onset suggests a preclinical phase in which non-clinical methods could be used in prediction. Consequently, routine postoperative measurement of serum level CRP is studied for infectious complications after colorectal surgery in general and anastomotic leak in particular. CRP and other biochemical parameters detect systemic reactions, while other techniques are recently applied to detect local, juxta-anastomotic changes in metabolism and ischemia. [6]

Microdialysis of the peritoneal cavity: This is a technique that uses an indwelling two-lumen catheter that detects changes in oxygenation locally at the site of the anastomosis. Few studies have shown the ability to distinguish patients with colorectal anastomosis after rectum resection from patients with an uncomplicated course, although these have insufficient samples to provide predictive values. [6]

Future solutions/studies should focus on preclinical detection of leaks since patients that are reoperated in an early phase could be protected from septic sequellae of anastomotic leak. [6]

Treatment

When facing and treating patients with an anastomotic leak, surgeons have to take into account many different aspects, *i.e.*, age, health status and current clinical condition of the patient, extent of dehiscence, the time between operation and reoperation, indication of primary resection, presence of diverting stoma and localization of the anastomosis. These variables lead to individualization of treatment strategies and incomparable outcome. However, few studies, showing that surgeons believe that the anastomosis can be repaired rather than dismantled, have paved the way for a trial in which next to mortality and morbidity, preservation of the anastomosis could be one of the endpoints Difficulties in designing such a trial are the aforementioned large variety of clinical course, the unpredictability of anastomotic leak and the relatively low incidence of anastomotic leak per center.

IDEAL SOLUTION STATEMENT

An effective, reliable and safe device that prevents the anastomotic leak in patients who undergo post intestinal resection regardless of the indication

NEED CRITERIA

MUST HAVE

- Must be effective in preventing anastomotic leak
- Must be safe to use without itself causing damage, peritonitis or sepsis intra-abdominally
- Must not cause obstruction of the bowel
- Must not in any way impede the surgeon's view or compromise the surgical field
- Must be applicable regardless of the indication of intestinal resection and anastomosis

NICE TO HAVE

- Must be affordable

- Must act as a preventive solution as well as alert in case of failure/leak
- Must be easy to use for a surgeon
- Must be applicable regardless of whether it is an open, laparoscopic or robotic procedure

REFERENCES:

1. Intestinal Anastomosis https://emedicine.medscape.com/article/1892319-overview
2. Murrell, Zuri A., and Michael J. Stamos. "Reoperation for anastomotic failure." *Clinics in colon and rectal surgery* 19.4 (2006): 213.
3. Hyman, Neil, et al. "Anastomotic leaks after intestinal anastomosis: it's later than you think." *Annals of surgery* 245.2 (2007): 254.
4. Erb L, Hyman NH, Osler T. Abnormal vital signs are common after bowel resection and do not predict anastomotic leak. *J Am Coll Surg*. 2014 Jun. 218 (6):1195-9
5. Akiyoshi T, Kuroyanagi H, Oya M, Konishi T, Fukuda M, Fujimoto Y, Ueno M, Miyata S, Yamaguchi T. Factors affecting the difficulty of laparoscopic total mesorectal excision with double stapling technique anastomosis for low rectal cancer. Surgery. 2009;146:483–489.
6. Daams, Freek, Misha Luyer, and Johan F. Lange. "Colorectal anastomotic leakage: aspects of prevention, detection, and treatment." *World Journal of Gastroenterology: WJG* 19.15 (2013): 2293.
7. Guyton, Kristina L., Neil H. Hyman, and John C. Alverdy. "Prevention of perioperative anastomotic healing complications: anastomotic stricture and anastomotic leak." *Advances in surgery* 50.1 (2016): 129.
8. Stergios, K., et al. "The potential effect of biological sealants on colorectal anastomosis healing in experimental research involving severe diabetes." *The Annals of The Royal College of Surgeons of England* 99.3 (2017): 189-192.
9. Endoluminal Vaccum Therapy https://www.bbraun.com/content/dam/b-braun/global/website/products-and-therapies/wound-closure/L74302_0916_Clinical_Evidence_Folder.pdf.bb-.98175420/L74302_0916_Clinical_Evidence_Folder.pdf Accessed 30/8/2018
10. Harvesting fat cells to repair anastomotic leaks http://colorectal.htc.nihr.ac.uk/ongoing-projects/harvesting-fat-cells-repair-anastomotic-leaks/ Accessed 30/8/2018
11. Trends in Operating Room Procedures in U.S. Hospitals, 2001–2011 https://www.hcup-us.ahrq.gov/reports/statbriefs/sb171-Operating-Room-Procedure-Trends.pdf

5. INTRAHEPATIC PRESSURE MEASUREMENT IN CHRONIC LIVER DISEASE

BACKGROUND

Cirrhosis, the end stage of any chronic liver disease, can lead to portal hypertension. Portal pressure increases initially as a consequence of an increased resistance to flow mostly due to an architectural distortion of the liver secondary to fibrous tissue and regenerative nodules. In addition to this structural resistance to blood flow, there is an active intrahepatic vasoconstriction that accounts for 20–30% of the increased intrahepatic resistance, and that is mostly due to a decrease in the endogenous production of nitric oxide. Portal hypertension leads to the formation of portosystemic collaterals. However, portal hypertension persists despite the development of these collaterals for 2 reasons: 1) an increase in portal venous inflow that results from splanchnic arteriolar vasodilatation occurring concomitant with the formation of collaterals; and 2) insufficient portal decompression through collaterals as these have a higher resistance than that of the normal liver. Therefore, an increased portal pressure gradient results from *both* an increase in resistance to portal flow (intrahepatic and collateral) and an increase in portal blood inflow. [1]

Direct measurement of portal pressure is highly invasive and no longer performed. The preferred, albeit indirect, method for assessing portal pressure is the wedged hepatic venous pressure (WHVP) measurement, which is obtained by placing a catheter in the hepatic vein and wedging it into a small branch or, better still, by inflating a balloon and occluding a larger branch of the hepatic vein. The WHVP has been shown to correlate very closely with portal pressure both in alcoholic and nonalcoholic cirrhosis. [1]

Nowadays, the most well-documented marker for portal venous pressure is HVPG measurement. There is data on the ability of HVPG to predict overall liver-related outcomes including risk for variceal hemorrhage. It has been proposed that serial HVPG measurement could assess fibrosis or cirrhosis despite etiology. Taken together, HVPG measurement can be used in the diagnosis of liver fibrosis, risk stratification, identification of patients with hepatocellular carcinoma, monitoring of the efficacy of medical treatment, and assessment of progression of portal hypertension. [2]

OBSERVATION

A 45-year-old female who was a known case of hepatitis C presented with melena (blood in stools) and 3 episodes of haematemesis (blood in vomitus) for one day. She had mild distention & diffuse tenderness of the abdomen. The patient was diagnosed with Decompensated liver disease with upper gastrointestinal bleeding due to ruptured esophageal varices. A large quantity of blood was drained through her nasogastric tube on lavage. The blood pressure was 100/50 and the pulse rate was 130 beats per minute despite IV fluid replacement and blood transfusion was advised. The patient was transfused with 3 pints of blood and was shifted for emergency variceal banding. Variceal banding was attempted and 3 bands were applied but were eventually discarded due to excessive bleeding due to lack of visibility and sclerotherapy

was done instead. Following sclerotherapy, an esophageal ulcer developed post-op supposedly due to mucosal involvement during banding.

THE PROBLEM

Antecubital, femoral, or right jugular veins are possible routes for insertion of a catheter in HVPG measurement. In case of right jugular vein insertion, a 6 French balloon catheter is placed in the right hepatic vein through a right jugular vein puncture for measurement of the FHVP. The WHVP is measured by inflation of the balloon catheter at the right hepatic vein. The WHVP is always corrected for increases in intraabdominal pressure (e.g., ascites) by subtracting the free hepatic vein pressure (FHVP) or the intraabdominal inferior vena cava pressure, which act as internal zeroes. The resultant pressure is the hepatic venous pressure gradient (HVPG), which is best accomplished with the use of a balloon catheter, usually taking triplicate readings and, when measured with a proper technique, is very reproducible and reliable. Since it is a measure of sinusoidal pressure, the HVPG will be elevated in intrahepatic causes of portal hypertension, such as cirrhosis, but will be normal in prehepatic causes of portal hypertension, such as portal vein thrombosis. In the normal liver, inter-connected sinusoidal network partially dissipates the pressure backup from the wedged catheter, and the WHVP is slightly lower than directly-measured portal pressure. In LC, the inter-sinusoidal communications are blocked by fibrous tissue, dissipation of pressure in the wedged vessels is insignificant and the WHVP accurately estimates portal pressure. The normal HVPG is 3–5 mmHg. The HVPG and changes in HVPG that occur over time have predictive value for the development of esophagogastric varices, the risk of variceal hemorrhage, the development of non-variceal complications of portal hypertension, and death. Single measurements are useful in the prognosis of both compensated and decompensated cirrhosis, while repeat measurements are useful to monitor response to pharmacological therapy and progression of liver disease.

Only minor complications such as mainly transient cardiac arrhythmias, local pain, or vagal reaction have been reported and these occur infrequently (< 1% of patients). HVPG measurements can be performed in 10 minutes with trans-jugular liver biopsy through the same route. Despite its advantages such as safety, feasibility, and reproducibility, the technique is invasive. Besides its invasive nature, limitations to the generalized use of HVPG measurement are low acceptance rate among patients with chronic liver disease and requires highly skilled technical expertise, the lack of expertise and poor adherence to guidelines will lead to the unreliable and irreproducible measurements. The invasiveness and technical difficulty greatly restrict its repeatable application. [1]

NEED STATEMENT

A simple, accurate, reliable non-invasive way to measure and monitor hepatic venous pressure in patients with chronic liver disease with cirrhosis and hepatocellular carcinoma for prognostication of patients in a tertiary care center.

FILTERING

Final score = 18

Rank = 5

MARKET POTENTIAL

Epidemiology: The Global prevalence of Cirrhosis ranges between 4.5 -9.5%.[1] Using an average of the two figures and considering an Indian population of 1,300,000,000 we could assume that the probable prevalence of cirrhosis due to any causes is 91,000,000. [3]

COMPETITIVE LANDSCAPE

CURRENT METHODS USED FOR DIAGNOSIS AND MONITORING LIVER DISEASE[1]

Various techniques have/are currently being used to monitor various pressure measurements within the liver as well as measure the amount of fibrosis which is a key reason for structural resistance to blood flow.

- **Wedged hepatic venous pressure (WHVP):** WHVP estimates portal venous pressure by occlusive hepatic vein catheterization. either with a wedge catheter or a balloon catheter.
- **Hepatic venous pressure gradient (HVPG)**: HVPG measurement is the best available method to evaluate the presence and severity of portal hypertension. Clinically significant portal hypertension is defined as an increase in HVPG to >10 mmHg.Currently, a safe, reproducible and less invasive technique to measure the HVPG has been developed. HVPG represents the gradient between the portal vein and the hepatic vein
- **Transient Elastography**: The device works by measuring shear wave velocity. In this technique, a 50-MHz wave is passed into the liver from a small transducer on the end of an ultrasound probe. The probe also has a transducer on the end that can measure the velocity of the shear wave (in meters per second) as this wave passes through the liver. The shear wave velocity can then be converted into liver stiffness, which is expressed in kilopascals. Essentially, the technology measures the velocity of the sound wave passing through the liver and then converts that measurement into a liver stiffness measurement; the entire process is often referred to as liver ultrasonographic elastography. [4]
- **Liver Biopsy:** The gold standard to stage fibrosis in the liver. It is used in diagnosing and grading liver diseases, and to guide therapeutic decisions. It can be performed either by percutaneous or transvenous (transjugular) routes. [3]
- **Computed tomography angiography:** A novel noninvasive assessment of hepatic venous pressure gradient and portal pressure using CTA performed with multi-detector CT scanners. [5]
- **Magnetic resonance elastography, multiparametric magnetic resonance imaging:** These techniques hold promise and are being investigated as surrogates of portal hypertension, particularly in patients who are not appropriate candidates for ultrasound elastography. [6]
- **Ultrasonography**: USG is the first-line imaging technique recommended for the diagnosis and follow-up of patients with portal hypertension since it is noninvasive, cheap and can be

performed at the bedside. The US is highly specific for the diagnosis of cirrhosis and portal hypertension, but its sensitivity is relatively low in compensated patients.[7]

- **Spleen stiffness:** Since splenomegaly in cirrhosis is a direct consequence of portal hypertension, spleen stiffness has been recently proposed as a new noninvasive parameter with better accuracy than liver stiffness for predicting clinically significant portal hypertension and esophageal varices. [7]

MANAGEMENT OF CIRRHOSIS

For individuals with compensated cirrhosis and mild portal hypertension, the AASLD provides the following guidance

- The treatment goal is to prevent the development of clinically significant portal hypertension (CSPH)/decompensation and, perhaps, even to achieve regression of cirrhosis.
- Elimination of the etiologic agent is the current mainstay of therapy.
- Drugs that act on portal flow, such as nonselective beta-blockers, will be mostly ineffective in this substage, given that the hyperdynamic circulatory state is not fully developed.

For individuals with compensated cirrhosis and CSPH but without gastroesophageal varices, the AASLD recommends the following:

- The goal of treatment should be to prevent clinical decompensation (ie, it is no longer the objective to prevent varices).
- No evidence exists at present to recommend the use of nonselective beta-blockers to prevent the formation of varices.

In patients with compensated cirrhosis and gastroesophageal varices, please refer to the esophageal varices Need specification document

IDEAL SOLUTION STATEMENT

A fast, non-invasive, accurate, reliable and affordable solution that allows for the measurement and repeated monitoring of the hepatic venous pressure in any patient by a clinician with chronic liver disease.

NEED CRITERIA

MUST HAVE

- Must be non-invasive
- Must be at least as accurate as HVPG
- Must be easy to implement allowing for repeated tests/follow up
- Must be at least as fast as HVPG (10 minutes)

NICE TO HAVE

- Must be portable (i.e. for an OPD setting)
- Must also gauge fibrosis (as accurately as elastography)
- Must be as affordable as an ultrasound scan

REFERENCES:

1. American College of Gastroenterology Guidelines Prevention and Management of Gastroesophageal Varices and Variceal Hemorrhage in Cirrhosis. Accessed 21/8/2018 https://gi.org/guideline/prevention-and-management-of-gastroesophageal-varices-and-variceal-hemorrhage-in-cirrhosis/
2. Suk, Ki Tae. "Hepatic venous pressure gradient: clinical use in chronic liver disease." *Clinical and molecular hepatology* 20.1 (2014): 6.
3. Global Burden Of Liver Disease: A True Burden on Health Sciences and Economies. World Gastroenterology Organization. Accessed 21/8/2018 http://www.worldgastroenterology.org/publications/e-wgn/e-wgn-expert-point-of-view-articles-collection/global-burden-of-liver-disease-a-true-burden-on-health-sciences-and-economies
4. Afdhal, Nezam H. "Fibroscan (transient elastography) for the measurement of liver fibrosis." *Gastroenterology & hepatology*8.9 (2012): 605.
5. Qi, Xiaolong, et al. "A novel noninvasive assessment of hepatic venous pressure gradient and portal pressure computed from computed tomography angiography." *Archives of medical science: AMS* 10.5 (2014): 1052.
6. Berzigotti, Annalisa. "Advances and challenges in cirrhosis and portal hypertension." *BMC medicine* 15.1 (2017): 200.
7. Annalisa Berzigotti, Susana Seijo, Enric Reverter & Jaime Bosch (2013) Assessing portal hypertension in liver diseases, Expert Review of Gastroenterology & Hepatology, 7:2, 141-155
8. Garcia-Tsao G, Abraldes JG, Berzigotti A, Bosch J. Portal hypertensive bleeding in cirrhosis: risk stratification, diagnosis, and management: 2016 practice guidance by the American Association for the study of liver diseases. *Hepatology*. 2017 Jan. 65 (1):310-35.

6. IATROGENIC URETERAL INJURY DUE TO LAPAROSCOPIC SURGERY

BACKGROUND

Iatrogenic (hospital-related) ureteral injury is a serious complication that can occur during abdominal or pelvic operations. Despite the low incidence rate (0.3% to 1.5%), ureteral injuries can lead to significant morbidity. Some studies identified risk factors such as resection of large pelvic masses, malignant neoplasms, inflammatory disease, previous operation, or radiation therapy. [1] In a study by Ostrzenski et. al. a total of 70 instances of ureteral injury during laparoscopic surgery were identified among 2491 reported cases. The 2491 cases of laparoscopy included case reports, small series of studies, as well as longer, consecutive studies. In 25.7% of cases, the initial laparoscopic procedures during which ureteral injury occurred were not described or specified. In cases in which the type of laparoscopic surgery was specified, 20.0% of the total cases of ureteral injury occurred during laparoscopically assisted vaginal hysterectomy (LAVH). A ureteral injury was identified intraoperatively in only 8.6% of cases, postoperatively in 70% of cases, and, in 21.4% of cases, the time of diagnosis was not specified. In instances in which the types of injury were described, transection occurred most commonly, accounting 20.0% of the injuries. Injuries most often occurred at or above the pelvic brim with Electrocautery involved in 17 of the 70 (24.3%) cases of ureteral injury. A laparotomy was used to repair the ureteral injury in 43 of 70 (61.4%) cases thus exemplifying the morbidity involved in the ureteral injury. [2] Ureteral injury is one of the most serious complications of gynecologic surgery. Less common than injuries to the bladder or rectum, ureteral injuries are far more serious and troublesome and are often associated with significant morbidity, the formation of ureterovaginal fistulas, and the potential loss of kidney function, especially when not recognized until postoperatively. For these reasons, injuries to the urinary tract, particularly the ureter, are the most common cause for legal action against gynecologic surgeons.[3]

OBSERVATION

An 80-year-old female patient had a history of a mass per rectum for the past 6 months. It was symptomatic for the past 3 weeks with fecal incontinence She underwent laparoscopic rectopexy with a mesh. The abdominal cavity is entered by using the Hasson approach. Once the camera port is inserted and the abdomen is insufflated, a right lower port and a right upper quadrant port was placed. A 30° scope was introduced into the umbilical port. To improve exposure, an additional port can be placed on the left flank. If the patient has a uterus that is affecting exposure, it can be retracted with a stitch to the anterior abdominal wall. Dissection is started posteriorly. The plane between the mesorectum and retroperitoneum is identified then the posterior pelvic plane under the superior rectal artery is entered, and the left ureter and hypogastric nerve plexus are identified; dissection is extended downward through the presacral anatomical space, all the way to the pelvic floor. The dissection must be carried below the Waldeyer fascia. Once the right stalk and posterior areas were mobilized, dissection proceeded anteriorly into the rectovaginal plane. The rectum was retracted to facilitates exposure. Subsequently, the rectum was mobilized anteriorly to the upper limit of the vagina. The rectum was then pulled out of the pelvis, and the location for fixation was assessed. A window was

made on the left side of the rectum to facilitate the rectopexy. A small rectangular sheet of polypropylene mesh was inserted via the right lower quadrant port and placed all the way down to the pelvic floor. The stalks were fixed to the sacrum and the mesh was incorporated. The patient presented with signs and symptoms of abdominal pain and fever with flank pain was present and a urethral injury was suspected. Immediate cystoscopy and retrograde pyelogram was performed for diagnosis of a suspected ureteral injury and was confirmed.

THE PROBLEM

A significant ureteral injury is defined as any recognized or unrecognized iatrogenic trauma to the ureter that prevents it from functioning properly or effectively. The injury may lead to acute ureteral obstruction (eg, a ureter that is inadvertently ligated) or discontinuity (ie, inadvertent ureteral resection). If an injury to the ureter has occurred and is unrecognized, it may lead to chronic ureteral obstruction (ie, crush injury, ischemia) or the formation of fistulas. Serious urinary complications after major operative laparoscopy were discovered in 1.6% of patients. This incidence compares favorably to serious urinary complications after standard gynecologic surgery. Intraoperative recognition of these complications will likely avoid additional surgery. Major operative laparoscopic procedures included hysterectomy, adnexectomy, treatment of tubal pregnancy, ovarian cystectomy, and ablation-fulguration of severe endometriosis (stage IV). The 6 most common mechanisms of operative ureteral injury are as follows:

- Crushing from misapplication of a clamp
- Ligation with a suture
- Transsection (partial or complete)
- Angulation of the ureter with secondary obstruction
- Ischemia from ureteral stripping or electrocoagulation
- Resection of a segment of ureter

Ureteral injuries may have numerous consequences, including the following:

- Spontaneous resolution and healing of the injured ureter
- Hydronephrosis: The urine from the ipsilateral kidney is prevented from draining into the bladder, leading to hydronephrosis and progressive deterioration of renal function. It may even have led to infection (pyelonephrosis)
- Ureteral necrosis with urinary extravasation: A section of the ureteral wall necroses (death of cells) due to pressure. This segment of the ureter eventually weakens, leading to urinary leakage into the surrounding tissues.
- Ureteral stricture formation: Strictures may lead to blockage of the ureter thus blocking the passage of urine
- Uremia: An end-stage emergency condition in which excess nitrogenous waste is present in the circulation due to renal dysfunction

The close anatomical relationship of the ureter with abdominal and pelvic organs increases the risk of injury. The course taken by the ureter in the pelvis is said to be ‘Fraught with Hazard’.

NEED STATEMENT

An accurate way to identify and continuously monitor the location of the ureter in any laparoscopic abdominal or pelvic procedure to avoid injury leading to further complications and morbidity.

FILTERING

Final score = 9

Rank = 7

MARKET POTENTIAL

Epidemiology: In laparoscopic surgeries, the ureteral injury rate is between 0.3% to 2%. Assuming 18 million laparoscopic surgeries a year and using 0.3% that would equate to around 5,400 cases of ureteral injury a year on average. The frequency of ureteral injury following gynecologic surgery too is approximately 1%, with a higher percentage of injuries occurring during abdominal hysterectomies and partial vaginectomies. Patients who have received pelvic radiation or who have advanced pelvic cancers requiring extensive surgical procedures are more likely to experience a ureteral injury. Ureteral injuries are seen during colorectal surgery too with incidence, ranging in the literature from 0.28–7.6%. Although the incidence is not high, the morbidity associated with ureteral injury is significant both in terms of the additional laparotomy required for repair as well as the medico-legal implications for the healthcare provider. [7]

COMPETITIVE LANDSCAPE

CURRENT METHODS OF URETERAL INJURY PREVENTION [1]

At present, four preventive measures are considered as having a high level of evidence (grade IA) according to major evidence-based guidelines:

- **Anatomical localization:** Requires a thorough understanding of intraoperative pelvic and retroperitoneal anatomy. [5]
- **Identification of peristalsis:** To distinguish the ureter from other vascular structures, the ureter will typically elicit peristalsis on gentle stroking. Others have observed that the ureter has a characteristic snap when it is gently palpated. [5]
- **Avoidance of electrothermal injury:** [5] Avoid using monopolar current close to the ureter. [5]

- **Preoperative intravenous pyelograms (IVP):** Although its usefulness is debatable, IVPs have been used preoperatively to locate the ureters for surgery in patients with disease processes that may distort the ureters, such as pelvic masses or inflammatory disease. [6]
- **Ureteral stenting:** Routine preoperative ureteral stenting has been advocated in cases where a difficult pelvic dissection is expected. However, recent reviews have shown that this measure does not affect the rate of ureteral injuries, even though it might help facilitate intraoperative detection of a respective lesion. Multiple catheters and stents exist in the market [5]
- **Lighted stents**: These have been used to assist in identifying the location of the ureters during laparoscopic surgery to help prevent iatrogenic injury. These have also found to be compelling during. [7]

MANAGEMENT OF SURGICAL SITE INFECTIONS

Depending on the type, duration, and location of the ureteral injury, surgical treatment may range from simple removal of a ligature to ureteroneocystostomy. The most common surgical treatments for ureteral injury are as follows:

- **Simple removal of a ligature:** If a clamp or ligature constricting the ureter is discovered, the clamp or ligature should be removed immediately, and the ureter should be examined. If ureteral peristalsis is preserved and damage is thought to be minimal, the ureter injury may be managed with observation.
- **Ureteral stenting:** If tissue ischemia or a partial transection of the ureteral wall is suspected, a ureteral stent should be placed. The purpose of the stent, which is typically placed cystoscopically, is to act as a structural backbone onto which the healing ureter may mold. It also guarantees drainage of urine from the renal pelvis directly into the urinary bladder. It also can work as a gentle dilator since it moves slightly in an up-and-down motion, associated with breathing, as the kidney unit moves. The use of the stent is thought to minimize the rate of obstruction of a ureteral stricture in the injured area. Ureteral stents have been shown repeatedly to act as an excellent scaffolding mechanism when a partial ureteral distraction has occurred, with excellent long-term patency rates.
- **Ureteral resection and ureteroureterostomy:** If extensive ischemia or necrosis is the result of an injury, the ureter injury is best treated by excising the injured segment of the ureter and reestablishing continuity with the urinary system. If the ureteral injury occurred above the pelvic brim, the simplest reconstruction is a ureteroureterostomy, a procedure that is indicated for injuries to short segments of the ureter (ie, < 2 cm), in which an anastomosis is performed between the 2 cut edges of the ureter. [8]
- **Transureteroureterostomy:** If ureteroureterostomy cannot be performed technically and the defect is too proximal in the ureter for ureteroneocystostomy, transureteroureterostomy may be performed. The literature also demonstrates the long-term efficacy of transureteroureterostomy. [8]
- **Ureteroneocystostomy:** If the ureteral injury occurred below the pelvic brim, where visualization of the ureter is difficult and where the vesical pedicles overlie the ureter, ureteroureterostomy is often too difficult to perform. In these cases, 2 types of ureteroneocystostomy procedures are indicated, either a psoas hitch or a Boari flap, in which the bladder is mobilized to reach the easily identifiable ureter proximal to the injury.

EMERGING SOLUTIONS

The future of distal ureteral injuries is exciting, and the use of new technology may change the management of distal ureteral injuries entirely.

Subintestinal submucosa (SIS): SIS can be used as a tissue scaffold, a new modality to treat ureteral injuries has emerged. While no current studies are being performed using SIS for the treatment of distal ureteral injuries, the placement of SIS may serve as a healing bridge between 2 injured ureteral ends. Although SIS will not drastically affect the management of short ureteral injuries or strictures, it may be useful in treating longer ureteral defects.

Robotic Surgery: Robotic techniques also have the potential for use in repair of ureteral injury. In a review of 43 cases of robot-assisted repair of injuries to the ureter or bladder that occurred during obstetrical and gynecological surgical procedures, Gellhaus et al concluded that robotic repair is associated with good outcomes, appears safe and feasible, and can be used immediately after injury recognition or as a salvage procedure after prior attempted repair. [9]

IDEAL SOLUTION STATEMENT

A solution that allows for localization and continuous monitoring of the ureter(s) during the entire surgical procedure and also allows for the intra-operative diagnosis of any ureteric injury

NEED CRITERIA

MUST HAVE

- Allows for localization of the ureter(s)
- Allows the continuous monitoring of the ureter(s) intra-operatively
- Should not cause any ureteric damage, injury or infection

NICE TO HAVE

- Should be integrated with the existing operation theatre technology
- Should be easy to administer and track
- Should be used to localize and monitor other hollow viscus structures besides the ureter
- Should allow for the intra-operative diagnosis of any ureteric injury

REFERENCES:

1. Palaniappa, Nandini C., et al. "Incidence of iatrogenic ureteral injury after laparoscopic colectomy." *Archives of surgery* 147.3 (2012): 267-271.

2. Ostrzenski, Adam, Bartholomew Radolinski, and Katarzyna M. Ostrzenska. "A review of laparoscopic ureteral injury in pelvic surgery." *Obstetrical & gynecological survey* 58.12 (2003): 794-799.
3. Teeluckdharry B, Gilmour D, Flowerdew G. Urinary Tract Injury at Benign Gynecologic Surgery and the Role of Cystoscopy: A Systematic Review and Meta-analysis. *Obstet Gynecol*. 2015 Dec. 126 (6):1161-9
4. Ureteral injury during gynecological surgery https://emedicine.medscape.com/article/454617-overview#a9 Accessed 10/8/2018
5. Muntener, Michael & Romero, Frederico & R. Kavoussi, Louis. (2006). Complications in Laparoscopic Surgery. Emergencies in Urology. 349-363. 10.1007/978-3-540-48605-3_28.
6. Chan, John K., Joelle Morrow, and Alberto Manetta. "Prevention of ureteral injuries in gynecologic surgery." *American journal of obstetrics and gynecology* 188.5 (2003): 1273-1277.
7. Boyan Jr, William P., et al. "Lighted ureteral stents in laparoscopic colorectal surgery; a five-year experience." *Annals of translational medicine* 5.3 (2017).
8. Miller EA. Ureteroureterostomy and Transureteroureterostomy. Smith JA Jr, Howards SS, Preminger GM, Eds. Hinman's Atlas of Urologic Surgery. 3rd ed. Philadelphia PA: Saunders; 2012. 747-50.
9. Gellhaus PT, Bhandari A, Monn MF, Gardner TA, Kanagarajah P, Reilly CE, et al. Robotic management of genitourinary injuries from obstetric and gynecological operations: a multi-institutional report of outcomes. *BJU Int.* 2014 Apr 21.

7. VASCULAR INJURIES DURING LAPAROSCOPIC SURGERY

BACKGROUND

Minimally invasive surgery (MIS) has provided surgeons with the opportunity to perform complex procedures with less morbidity and good outcomes. However, it is not without its associated potential complications. The types of complications range from more minor ones such as difficulty accessing the abdominal cavity (incidence rates 0.2–3.1%) to those with significant morbidity such as vascular and organ injuries (incidence rates from 0.5% to as high as 20% depending on the type of MIS). While these complications rates may appear low, the number of patients affected is great, given the number of MIS procedures performed each year. [1] Vascular injuries during laparoscopic surgeries are rare, seen in 0.2 in 1000 cases, however, they are associated with 6–13% morbidity and mortality. The injuries maybe major/catastrophic injuries or minor vascular injuries. [2] Inadvertent bleeding causes non-reimbursable hospital costs amounting to billions of dollars in the US every year. [3]

OBSERVATION

49-year-old male patient with a history for asymptomatic cholelithiasis for the past one year. 6 days ago he presented with a history of jaundice, fever and abdominal pain. He was diagnosed with acute cholecystitis and was treated symptomatically and with antibiotics for 6 days. He was posted for laparoscopic cholecystectomy once the symptoms subsided. The patient was under GA. A 1.5-cm longitudinal incision is made at the inferior aspect of the umbilicus, then deepened through the subcutaneous fat to the anterior rectus sheath. The peritoneum is elevated between two straight clamps and incised so as to afford safe entry into the abdominal cavity. An 11-mm blunt Hasson trocar is placed into the abdominal cavity, and insufflation of carbon dioxide is initiated to a maximum pressure of 15 mm Hg. A 1.2-cm incision is made three fingerbreadths below the xiphoid process and deepened into the subcutaneous fat. An 11-mm trocar is advanced into the abdominal cavity under direct vision in the direction of the gallbladder through the abdominal wall. A 5-mm grasper is placed through the 11-mm subxiphoid port and applied to the fundus of the gallbladder. The gallbladder is then elevated over the dome of the liver to facilitate the positions for the lateral 5-mm ports. Lateral skin incisions are made, and two 5-mm trocars are advanced into the peritoneal cavity under direct vision. A 5-mm grasper with the locking mechanism is placed through each of these lateral ports. Due to the **inflammatory reaction, all anatomical landmarks and surgical fields were lost**. There was **extensive fibrosis and scar tissue adhering the gallbladder to the liver**. The surgeon dissected for 2 hours until he located the cystic duct and cystic artery. While dissecting due to lack of visualization and confirmation he **lacerated the cystic artery and led to an arterial bleed**. The procedure was converted to an open surgery and on laparotomy, the bleeding site was eventually identified and clamped to control the bleeding. One pint of blood was transfused due to the drop in blood pressure. The **cystic duct was then identified and clamped** and the gallbladder dissected and separated from the liver before being removed from the port. The patient was admitted to the ICU postoperatively for observation for 2 days.

THE PROBLEM

Vascular injuries during laparoscopic surgeries are rare, seen in 0.2 in 1000 cases, however, they are associated with 6–13% morbidity and mortality. The injuries maybe major/catastrophic injuries or minor vascular injuries. Commonest sites for catastrophic hemorrhage are the right iliac vessels, inferior vena cava and less commonly the abdominal aorta. Access is associated with injuries to the gastrointestinal tract and major blood vessels and at least 50% of these major complications occur prior to the commencement of the intended surgery. The injuries commonly occur at the step of abdominal entry using a Veress needle or the insertion of trocars. These risks are inherent to all laparoscopic surgery. The management of major vascular injuries requires an open surgery/laparotomy and vascular surgeons. [2] This complication rate has remained the same during the past 25 years. [4] 13-50% of vascular injuries are undiagnosed at the time of surgery. [4] The reason for these injuries is the close proximity of the anterior abdominal wall to the retroperitoneal vascular structures. In thin patients, this distance may be as little as two centimeters. The distal aorta and right common iliac artery are particularly prone to injury.

Minor vascular injuries are so named since these are injuries to vessels of lesser importance than the aorta, inferior vena cava, and iliac vessels. However, these are by no means minor in nature. The most common minor vascular injury is to the inferior epigastric vessels, occurring in up to 2.5% of laparoscopic hernia repairs. There were 76 cases of minor vascular injuries involving principally the epigastric vessels in a review of 10,837 patients undergoing a hernia repair. [4]

Factors responsible: [4]

1. Surgical experience
2. Unsharpened trocar
3. Failure to stabilize abdominal wall
4. Perpendicular insertion of needle or trocar
5. Lateral deviation of needle or trocar
6. Inadequate pneumoperitoneum
7. Forceful thrust
8. Failure to locate anatomical landmarks
9. Inadequate incision size

The injuries are often due to fundamental challenges associated with using laparoscopic surgery, where the field of surgery has bleeding, fat, scar tissue and adhesions. These problems are exacerbated by complicating factors such as inflammation, cancer, chronic disease, obesity, and re-operations. [4]

Although some devices exist, the main limitations of existing vascular detection systems include the inability to quantitate vessel metrics, added complexity during surgery, and cost. [5]

NEED STATEMENT

An accurate, affordable way to detect vascular structures (arterial and venous) peri-operatively (insertion of trocars and/or intra-operatively) in laparoscopic surgery to avoid laceration of said vascular structures during any laparoscopic abdominal or pelvic procedure to avoid injury leading to complications related to blood loss, conversion to laparotomy and possible mortality.

FILTERING

Final score = 8.5

Rank = 8

MARKET POTENTIAL

Epidemiology: In laparoscopic surgeries, the major vascular injury rate ranges from 0.1 to 0.64 per 1000 cases 1800-12000 Assuming 18 million laparoscopic surgeries a year this would equate to around 1800 – 12,000 cases of major catastrophic vascular injury a year on average. This excludes the so-called minor vascular injuries which are much more commonplace and can lead to complications such conversion to laparotomy, blood loss, poor surgical outcomes and increased costs.

COMPETITIVE LANDSCAPE

CURRENT METHODS OF VASCULAR INJURY PREVENTION [1]

Prevention is particularly important in laparoscopic surgery with its two-dimensional vision and limited tactile feedback, it is essential to adhere to general surgical principles of a meticulous dissection [5]

- **Anatomical localization:** Requires a thorough understanding of intraoperative pelvic and retroperitoneal anatomy. [6]
- **Intraoperative vessel visualization** (ultrasound, fluorescence angiography) are insufficient based on one or a combination of the following: inherent technical limitations (i.e. resolution, speed, etc.) of the technology, inability to easily integrate into the surgical workflow, cost constraints, and/or added personnel requirements for equipment operation and/or analysis of test results. [3]
    - **Laparoscopic ultrasound:** Lack sensitivity and are limited to detection to detection of large vessels
    - **Laser Doppler probes:** Lack sensitivity and are limited to detection to detection of large vessels
    - **Near-infrared (NIR):** Used in breast reconstruction and colon surgery to offer information about the microvasculature, but offers low sensitivity and requires expensive contrast agents
- **Smart Laparoscopic grasper:** Blood vessels ranging from 2 to 6 mm and buried under up to 1 cm of tissue can be detected [3]

MANAGEMENT OF VASCULAR INJURIES

Management of vascular injuries during MIS is often difficult due to the limited visibility and morbidity produced by these procedures. [1]

Whereas in access-related vascular injuries it is recommended to convert to open surgery in order to control the bleeding, vascular injuries that occur during dissection after all the ports have been placed may be dealt with laparoscopically. The range of appropriate measures goes from simple application of pressure to immediate conversion to open surgery. Obviously, the optimal management of an intraoperative vascular complication depends on the severity of the case and the experience of the surgeon. In the individual case, the surgeon must make this decision based upon the respective situation and must choose the solution that least compromises patient safety and the goals of the actual procedure. [4]

As in open surgery, the first step is the application of pressure to the source of the bleeding. Whereas in open surgery manual compression can be applied very quickly, in a laparoscopic case an effective tamponade requires a small laparotomy pad or at least a sponge gauze to be pressed onto the bleeding site via a laparoscopic instrument (e.g., a grasper). As an alternative, Yurkanin suggested the use of a Foley catheter that is inserted through one of the ports. The inflated catheter balloon can be pressed onto the bleeding site with a catheter guide (Yurkanin et al. 2005). Moreover, the intraabdominal pressure can be increased up to 25 mmHg temporarily to diminish venous bleeding. Blood pooling around the site of the lesion can then be aspirated and a slow retraction of the tamponade should reveal the source of the bleeding. In a minor vascular injury, application of pressure for a couple of minutes alone may solve the problem.[5]

Hemostyptic agents: Agents such as oxidized regenerated cellulose, and fibrin glue may be applied alone or in combination. [5]

Electrocautery or harmonic scalpel: The harmonic scalpel uses a high-frequency ultrasonic transducer with a microprocessor-controlled generator to detect changes in the feedback acoustic pattern. Vessel coagulation is then performed in a similar method to electrosurgery by tamponading the vessel and then sealing with a denatured protein coagulum while using ultrasonic vibration to denature hydrogen bonds. [6]

Application of clips: If there is adequate exposure of the injured vessel, these techniques may be enough to control the bleeding. [5]

Suturing: A decision must be made as to whether the respective blood vessel has to be repaired or not. If a repair is not necessary, an open or a laparoscopic suture ligation is most likely to stop the bleeding. Suture appliers such as Lapra-ty may be used to save time.

Hem-o-locks: The Hem-o-lok product line is an innovative ligation system that combines the security of a 2.0 suture with the speed of a metal clip for open and laparoscopic surgery

Ligasure and Gyrus PK: These devices use bipolar electrical energy and pressure to melt collagen and elastin in vessel walls to form a seal. The former utilizes continuous energy while the latter uses pulsed energy. [6]

Enseal: This device uses bipolar electrical energy but employs a nanotechnology feedback mechanism to reduce thermal spread by changing the energy required for sealing in response to tissue characteristics [6]

Gel Foam: This is a Sterile Compressed Sponge intended for application to bleeding surfaces as a hemostatic. [7]

Floseal: The Floseal Matrix is indicated in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical. [8]

Stapling devices: In case the injured vessel is nicely exposed, the application of a stapling device might also be considered. [5]

Conversion to open surgery: Endoscopic management is more likely to be feasible if a repair does not have to be attempted to Obtain optimal exposure: Identification of the bleeding site isolate site. In most cases of major vascular injury, however, it is advisable to convert to an open procedure and consider the consultation of a vascular surgeon. [5]

IDEAL SOLUTION STATEMENT

An affordable solution that allows for the accurate localization of blood vessels during the insertion of trocars as well as allows for the continuous monitoring of vessels intraoperatively especially when the field of surgery has active bleeding, fat, scar tissue and adhesions.

NEED CRITERIA

MUST HAVE

- Allows for localization of the vessels (regardless of diameter)
- Provides continuous monitoring of vessels intraoperatively when the field of surgery has bleeding, fat, scar tissue and adhesions
- Should not cause any ureteric damage, injury or infection
- Must be affordable
- Should not complicate the procedure
- Should not be time-consuming and delay the surgery

NICE TO HAVE

- Should be integrated with the existing operation theatre technology
- Should be easy to administer and track
- Should not require additional technical staff/training

REFERENCES:

1. Passerotti, Carlo C., et al. "The effectiveness of a systematic algorithm for the management of vascular injuries during the laparoscopic surgery." *Current urology* 9.3 (2015): 138-142.
2. Asfour, Victoria, Edward Smythe, and Rizwan Attia. "Vascular injury at laparoscopy: a guide to management." *Journal of Obstetrics and Gynaecology* (2018): 1-9.
3. Chaturvedi, Amal, et al. "Blood vessel detection, localization and estimation using a smart laparoscopic grasper: a Monte Carlo study." *Biomedical optics express* 9.5 (2018): 2027-2040.
4. Krishnakumar, S., and P. Tambe. "Entry complications in laparoscopic surgery." *Journal of gynecological endoscopy and surgery* 1.1 (2009): 4.
5. Muntener, M., F. R. Romero, and L. R. Kavoussi. "Complications in laparoscopic surgery." *Emergencies in Urology*. Springer, Berlin, Heidelberg, 2007. 349-363.
6. Lamberton, Gregory R., et al. "Prospective comparison of four laparoscopic vessel ligation devices." *Journal of Endourology*22.10 (2008): 2307-2312.
7. http://www.pfizer.com/files/products/uspi_gelfoam_plus.pdf Accessed 20/8/2018
8. http://www.floseal.com/us/ Accessed 20/8/2018

8. NERVE TRAUMA DURING HEAD & NECK SURGERY

BACKGROUND

Neck dissection can lead to trauma to the greater auricular, marginal mandibular, spinal accessory nerve, phrenic and vagus nerve while thyroid surgery can lead to trauma to the external branch of superior laryngeal nerve and recurrent laryngeal nerve. The incidence of transient temporary injury to the recurrent laryngeal nerve is 5% and permanent damage is seen in 2-3% of thyroid surgeries, the most important causes being the accidental transection of the nerve. A safer,(compared to dissection) more accessible (compared to continuous Electrophysiological monitoring) way to identify and skeletonize the recurrent laryngeal nerve during head and neck surgery to avoid intra-operative damage. [1] The incidence of permanent facial nerve paralysis or paresis after surgery for benign parotid tumors is between 3% and 5%, 1% in primary ear surgery and about 4-10% in revision cases. [2]

Unilateral RLN injury results in paralysis of the respective vocal cord. Bilateral RLN injury can either lead to a reduction of the glottic airspace and may require a tracheostomy or widening of the airspace leading to aspiration into the lungs. Injury to the greater auricular nerve leads to loss of sensation in the skin in an around the pinna of the ear. Marginal mandibular nerve injury can lead to salivary incontinence and changes in the muscles in and around the lips thus causing inability to lower the lip and aesthetic complications. Spinal accessory nerve supplies the trapezius and sternocleidomastoid muscle thus leading to shoulder dysfunction. [1] Facial nerve injury can lead to a deformity causing obvious and disfiguring complications. The medicolegal implications and the delayed and guarded recovery of such patients leave a bad scar, not only on the patient but also on the surgeon. [3]

OBSERVATION

A 45-year-old woman presented with goiter for the last 3 years which presented with compressive symptoms. Euthyroid. Access, ports, and operative space creation: Surgical access can be broadly classified as cervical and extra cervical routes. Within the extra cervical route, TA, CW, and AB approaches are more frequently practiced. It is still early days to comment on the superiority of one technique over the other. Usually, a 10 mm camera port and two 5 mm working ports are used with an additional port optionally. Irrespective of the access route, operative space (OS) has to be created in contrast to natural OS in the abdomen or pleural cavity. We create OS through a combination of blunt and sharp subcutaneous or subpectoral fascial dissection with long hemostats, balloon inflation, and diathermy dissection under vision (Fig. 2). This dissection is continued in the subplatysmal plane of the neck beyond. the clavicle. This latter dissection is done up to the level of the thyroid cartilage and over the ipsilateral thyroid lobe. Reaching thyroid gland in visceral space of neck: In ET, similar to open thyroidectomy, the thyroid goiter (TG) can be approached through midline between strap muscles or lateral approach between strap muscle and sternocleidomastoid (SCM) muscle. This lateral approach is especially useful in ET as it is an avascular plane, avoids anterior jugular veins, and aids in direct control of middle thyroid vein. With diathermy, the deep fascia over this plane is incised and SCM is retracted. Lateral one-third of strap muscles can be cut for extra space. Middle thyroid vein is controlled with clips. Mobilization of the thyroid gland: Deep-to-deep cervical fascia, the

avascular plane between thyroid lobe and carotid sheath, is further opened up till prevertebral fascia. Pretracheal fascia over the thyroid lobe is teased close. to TG and it is rotated medially. This dissection continues until the lateral part of the superior thyroid pedicle is visualized. Control of superior thyroid pedicle: Strap muscle overlying the TG is retracted and if needed its lateral one-third is cut. Once superior pedicle blood vessels are visualized, they must be skeletonized, teasing away the pretracheal fascia and strap muscle fibers with bipolar diathermy. The skeletonized pedicle blood vessels are individually double clipped on the proximal side and single clipped toward TG. They are divided to devascularize TG superiorly Control of inferior thyroid pedicle: With the combination of blunt and sharp dissection assisted by diathermy, the trachea below the ipsilateral isthmolobar junction is visualized. The multiple inferior thyroid veins (ITVs) should be skeletonized from the medial to the lateral side. ITVs are individually clipped and divided. Before dividing the lateral most ITV, it is mandatory to differentiate it from recurrent laryngeal nerve (RLN) as it courses parallel to them. If in doubt, lateral ITV should be divided after demonstration of RLN only. However, with the endoscopic magnification, it is not as difficult to differentiate ITV from RLN as in open surgery. Identification of recurrent laryngeal nerve (RLN): As ET is usually performed for smaller goiters, RLN lies in normal location in the majority of cases. It courses in the trachea-esophageal groove between the branches of ITA. With endoscopic magnification, RLN is seen very clearly as a white string-like structure with a vasa nervosum accompanying it, posterior to TG. Low-amperage diathermy current is employed at least 2 mm away from RLN to divide vascular structures. RLN is followed up, until its entry at the lower border of the inferior pharyngeal constrictor. Parathyroid glands (PT): Thorough anatomical and embryological knowledge along with adequate experience in thyroid surgery is mandatory to identify PT. They should be looked for in usual anatomical locations. Superior PT, which is the most constant, is located posterosuperior to RLN in more than 80 % of individuals. Capsular dissection close to the capsule of TG with meticulous hemostasis using bipolar diathermy is done to preserve PT. Inferior PT is located anteroinferior to RLN over the inferior pole of the thyroid, which is dissected and preserved similar to superior PT. Ligament of Berry: Division of posterior suspensory ligament of thyroid also known as ligament of Berry is the penultimate step of ET. After identification of RLN over its entire course, the ligament of Berry has divided close to TG and away from RLN using bipolar diathermy, as it is a vascular structure. Separation of TG from thyroid bed: The only attachment of TG in the neck after prior steps is flimsy, hypovascular areolar tissue between TG and tracheal perichondrium. It is dissected with sharp dissection using scissors after the elevation of TG off the trachea. Postoperatively the patient presented acute respiratory distress and was diagnosed with unilateral recurrent laryngeal nerve injury. She was admitted to the ICU and started on systemic corticosteroids

THE PROBLEM

Thyroid surgery is the most common cause of recurrent nerve (RLN) injury and gives a rate approaching 5% in a large series with close follow-up. These complications are probably more common in revision neck surgery. The course of the RLN frequently varies despite normal anatomy or as a consequence of congenital vascular anomalies or distortion of regional anatomy by extension of goiter by neoplasm or inflammation. When approaching the inferior pole of the

gland, the RLN may be traversed by the ITA (inferior thyroid artery) or may pass between the arterial ramifications. Deliberate identification of the RLN minimizes the risk of injury. When the nerve is identified and dissected, the reported RLN injury rate during thyroidectomy is 0-2.1%. This rate is reportedly higher if surgery is repeated (2- 12%) or if the nerve is not clearly identified (4-6.6%). [4] Unilateral RLN injury can cause varying degrees of hoarseness, microaspiration, coughing and other symptoms, and bilateral RLN injuries may induce aphonia, dyspnea, and even asphyxia to threaten the life of the patients.

Facial nerve injury is a feared complication of parotidectomy. Facial nerve paralysis can cause cosmetic and functional morbidity, ocular complications, diminished quality of life, and medical malpractice litigation.1,2 Temporary facial nerve dysfunction occurs in 20% to 40% of patients undergoing parotidectomy, whereas permanent facial nerve dysfunction is uncommon and occurs in 0% to 4% of patients. Even the most experienced surgeon may have difficulty identifying and preserving cranial nerves. [5] Oral and maxillofacial surgical procedures accounted for 40% of injuries, resections of head and neck lesions 25%, otologic procedures 17%, cosmetic procedures 11%, and other procedures 7%. [6] There are numerous factors that may influence facial nerve injury during parotidectomy, including tumor size, type, location, extent of surgery, inflammation, and reoperation. Facial nerve injury mechanisms during parotidectomy include nerve division, stretch, compression, ligature entrapment, thermal and electrical injuries, and ischemia. The surgeon has control over most of these mechanisms of facial nerve injury, and proper, a safe surgical technique is paramount for facial nerve preservation. [5]

One should also consider the possibility of any thermal injury, either due to the cautery or the burr as a source of injury, if he feels that the nerve is intact anatomically. A remote possibility of Bell's palsy should also be considered but only as a diagnosis of exclusion.

With the advent of high-quality microscopes and nerve monitors, the chances of iatrogenic facial nerve palsy have come down dramatically but complications still occur leading to poor surgical outcomes and medico-legal cases.

NEED STATEMENT

A safer and more accessible way to identify, skeletonize and avoid injury during dissection to the nerves (especially facial & recurrent laryngeal nerves) during head and neck surgery to avoid intra-operative damage and further complications.

FILTERING

Final score = 8.5

Rank = 9

MARKET POTENTIAL

Although the data is not available for India, in the USA in a National Trends in Thyroid Surgery study it was found that 507,356 thyroid surgeries were performed between 2001 and 2008. [7] With an incidence rate of 0.2 – 1% it would mean close to 3,000 RLN injuries if one considers an average incidence rate of 0.6%. [4]

In a chapter on Medicolegal aspects of iatrogenic facial nerve injury, they cited a large-volume center which reported that 102 patients with iatrogenic injury seen over a 10-year. period.

Besides for the obvious medical complications seen in iatrogenic nerve injuries, the medicolegal complications are also important and the same study above mentioned that malpractice and negligence cases are not uncommon especially with facial nerve injury.

COMPETITIVE LANDSCAPE

CURRENT METHODS USED FOR PREVENTION NERVE TRAUMA INTRAOPERATIVELY

The risk of inadvertent nerve trauma due to accidental transection or heat-related injury may be minimized by the following means:

Surgical Technique: For facial nerve antegrade technique or retrograde technique or combination of techniques may be used to avoid injury to the nerves. [9]

Nerve monitoring: This is an adjunctive method that a surgeon can choose to use during surgery to assist with the functional preservation of a motor nerve or nerves. Facial nerve monitoring is widely used in otologic, neurotologic, and skull base surgery. Improvement in the functional preservation of the facial nerve with facial nerve monitoring in acoustic neuroma surgery and its cost-effectiveness in otologic surgery has been demonstrated. It is also used in parotid surgeries. The goals of facial nerve monitoring during parotidectomy are the same as those during otologic and neurotologic surgery and include early facial nerve identification, warning to the surgeon of unexpected facial nerve stimulation, mapping of the course of the nerve, reduction of mechanical trauma to the nerve, and evaluation and prognosis of nerve function at the conclusion of the procedure. [5]

Monitoring methods:

1. **Visual Monitoring:** One approach is to visually monitor for facial movements during surgery. With this method, an assistant alerts the surgeon to facial movements that are evoked electrically with a nerve stimulator or evoked mechanically during surgical dissection. [5]

2. **Electrophysiological monitoring**: This is another more sophisticated method of facial nerve monitoring. With this approach, facial muscle electromyographic (EMG) activity is monitored by an electrophysiologist or by the surgical team during surgery. Several electrophysiologic nerve monitoring systems are commercially available, including the NIM-Response 2.0 Nerve Integrity Monitor (NIM-2; Medtronic Xomed, Jacksonville, FL), the Neurosign 400 (Magstim Co., Ltd, Whitland, South West Wales, UK), and the Viking II–EMG

System (Nicolet Biomedical, Madison, WI). These multichannel systems continuously track facial muscle activity during surgery and have a built-in pulse generator for electrically evoked EMG responses. Electrophysiologic monitoring is generally the preferred method of facial nerve monitoring because it is more sensitive and specific than visual monitoring of facial movements. Intraoperatively, the surgeon or the neurophysiologist performing the monitoring must differentiate true EMG events from artifacts such as those that occur from contact between surgical instruments in the operative field. EMG waveform characteristics, EMG amplitude, and the surgical context of the event aid in this differentiation. A false-positive event should be excluded because this may give the surgeon a false sense of insecurity. It must be emphasized that the absence of an electrically evoked response does not exclude the possibility that the stimulated tissue is the facial nerve. Electrosurgical units and other electrical equipment can create an electrical artifact that interferes with facial muscle response recording. [5]

Intraoperative neuromonitoring of RLN has brought the following benefits: significantly reducing iatrogenic RLN injury, increasing the scope of surgical safety, improving the identification rate of RLN, accelerating the intraoperative RLN identification and reducing accidental injury

Electrode stimulations for RLN and Superior laryngeal nerve: Recording electrodes are positioned to monitor both the right and left vocal folds. An identical fine silver wire electrode is used, applied to the vocal folds. The RLN is stimulated by the application of a unipolar brass probe to deliver an electric current that ranged from 0.5 to 1.5 mA at a frequency of 30 Hz. The identity of an intact RLN would be confirmed through a series of audible acoustic signals that were generated by the machine and an action potential traced on a monitor screen. The functional integrity of the nerve once again should be confirmed at the end of the thyroidectomy by the testing of the most proximal exposed portion of the nerve.

3. **Pulsed Infrared Optical Radiation**: Facial nerve monitoring equipment of the future will likely be more refined. A recent report describes optical nerve stimulation using pulsed infrared optical radiation. This new method may contribute to the improved spatial selectivity of stimulation. [5]

4. **Modalities used in other surgical fields:** In a study among Patients undergoing surgical fixation following acetabular or pelvic fracture, they had Neuromonitoring during surgery performed using three different modalities, transcranial electric motor evoked potential (tceMEP), somatosensory evoked potential (SSEP), and electromyographic (EMG) monitoring. tceMEP monitoring was found to be 100% sensitive and 86% specific at detecting an impending nerve injury. The sensitivity and specificity of SSEP were 75% and 94%, while EMG sensitivity was unacceptably low at 20% although specificity was 93%. [10]

MANAGEMENT OF NERVE INJURY

Facial Nerve: Once there is iatrogenic facial paralysis, it is recommended to re-explore as early as possible, provided adequate facilities (experienced otologist and well-equipped operation theater) are available. Facial nerve exploration surgery is often necessary to restore facial nerve functions. The indications and the timing of exploration surgery are sometimes controversial. In general, facial nerve exploration by means of decompression with or without restoration of the continuity of the nerve is performed when there is immediate complete facial nerve injury after mastoidectomy or parotid surgery. However, when the palsy is incomplete, a wait -and -see policy is generally indicated. The final results depend on the extent of the injury. If there is a total transaction with gap requiring cable nerve grafting, then the results are less than optimum, with significant synkinesis. A greater auricular nerve graft may be done, because of its close proximity to the operative site and because of ease of harvesting. If anatomical continuity is maintained, the results are good with minimum synkinesis. [3, 11]

Recurrent Laryngeal Nerve: The treatment methods include the medicines (neurotrophic medicines, glucocorticoids and vasodilators); ultrashort wave therapy, acupuncture and moxibustion and others; voice training, vocal cord injection and others; reinnervation methods of the unilateral RLN injury (including RLN decompression, end to end anastomosis of RLN, main branch of ansa cervicalis to RLN anastomosis, implantation of ansa cervicalis-nerve muscular pedicle. [12]

IDEAL SOLUTION STATEMENT

An accurate, reliable and safe device that allows for the continuous identification and functional integrity of the nerve to allow for the same dissection including the use of heat based instrumentation during any head and neck surgery.

NEED CRITERIA

MUST HAVE

- Must be accurate and precise identifying and localizing the nerve
- Must be very sensitive and specific (no/minimal false positives and false negatives)
- Must allow for the monitoring of the functional integrity of the nerve
- Must not in any way impede the surgeon's view or compromise the surgical field

NICE TO HAVE

- Must be applicable in other similar procedures where an iatrogenic injury is possible
- Must be easy to use
- Must be able to identify neural and vascular tissue
- Must be portable enough to be shifted to different operation theatres

REFERENCES:

1. Complications in Head and Neck Surgery, Pratemesh Pai. Otorhinolaryngology Clinics, Jan – April 2010 ; 2(1) 61-67
2. Facial nerve monitoring in parotid surgery: The standard of care? Robert L. Witt, MD, FACS
3. Otolaryngology–Head and Neck Surgery Vol 119, Issue 5, pp. 468 – 470
4. Kumar, Rakesh, et al. "Iatrogenic facial nerve palsy" Prevention is better than cure": Analysis of four cases." *Indian Journal of Otology* 17.4 (2011): 170.
5. Zidan, Mohammed Fatehy, and Ahmed Abdou Moustafa. "Laryngeal Nerves Monitoring Versus Non-monitoring in Thyroid Surgery." *Egyptian Journal of Hospital Medicine (June 2010)* 39: 249-259.
6. Eisele, David W., Steven J. Wang, and Lisa A. Orloff. "Electrophysiologic facial nerve monitoring during parotidectomy." *Head & neck* 32.3 (2010): 399-405.
7. Hohman, Marc H., Prabhat K. Bhama, and Tessa A. Hadlock. "Epidemiology of iatrogenic facial nerve injury: a decade of experience." *The Laryngoscope* 124.1 (2014): 260-265.
8. Loyo, Myriam, Ralph P. Tufano, and Christine G. Gourin. "National trends in thyroid surgery and the effect of volume on short-term outcomes." *The Laryngoscope* 123.8 (2013): 2056-2063.
9. Guntinas-Lichius and Schaitkin, Facial Nerve Disorders and Diseases: Diagnosis and Management (ISBN 978-3-13-175181-2)
10. O'Regan, Barry, Girish Bharadwaj, and Andrew Elders. "Techniques for dissection of the facial nerve in benign parotid surgery: a cross specialty survey of oral and maxillofacial and ear nose and throat surgeons in the UK." *British Journal of Oral and Maxillofacial Surgery* 46.7 (2008): 564-566.
11. Porat, Manny, et al. "Neurophysiologic monitoring can predict iatrogenic injury during acetabular and pelvic fracture fixation." *HSS Journal*® 9.3 (2013): 218-222.
12. Asma, Asma, et al. "Iatrogenic facial nerve palsy: lessons to learn." *Singapore Med J* 50.12 (2009): 1154-1157.
13. Jiang, Yan, et al. "Prevention and treatment of recurrent laryngeal nerve injury in thyroid surgery." *International journal of clinical and experimental medicine* 7.1 (2014): 101.

9. ESOPHAGEAL VARICEAL BLEEDING

BACKGROUND

Chronic liver disease is prevalent worldwide irrespective of age, sex, region or race. Cirrhosis is an end result of a variety of liver diseases characterized by fibrosis and architectural distortion of the liver and can have varied clinical manifestations and complications. According to WHO, about 46% of global diseases and 59% of the mortality is because of chronic diseases and almost 35 million people in the world die of chronic diseases. Liver disease rates are steadily increasing over the years. [1]

Global prevalence of cirrhosis from autopsy studies ranges from 4.5% to 9.5% of the general population that would equate to more than 50 million people in the world. Globally, alcohol, NASH, and viral hepatitis currently are the most common causative factors. Prevalence of cirrhosis is likely to be underestimated as almost a third of the patients remain asymptomatic.. Deaths from cirrhosis have been estimated to increase and would make it as the 12th leading cause of death in 2020. [1]

Gastroesophageal varices are the most relevant portosystemic collaterals because of their rupture results in variceal hemorrhage, the most common lethal complication of cirrhosis. Gastroesophageal varices are present in approximately 50% of patients with cirrhosis. Their presence correlates with the severity of liver disease. [2]

Patients without varices develop them at a rate of 8% per year. Variceal hemorrhage occurs at a yearly rate of 5–15% and the most important predictor of hemorrhage is the size of varices, with the highest risk of first hemorrhage (15% per year) occurring in patients with large varices. Although bleeding from esophageal varices ceases spontaneously in up to 40% of patients, and despite improvements in therapy over the last decade, it is associated with a mortality of at least 20% at 6 weeks.

OBSERVATION

A 45-year-old female who was a known case of hepatitis C presented with melena (blood in stools) and 3 episodes of haematemesis (blood in vomitus) for one day. She had mild distention & diffuse tenderness of the abdomen. The patient was diagnosed with Decompensated liver disease with upper gastrointestinal bleeding due to ruptured esophageal varices. A large quantity of blood was drained through her nasogastric tube on lavage. The blood pressure was 100/50 and the pulse rate was 130 beats per minute despite IV fluid replacement and blood transfusion was advised. The patient was transfused with 3 pints of blood and was shifted for emergency variceal banding. Variceal banding was attempted and 3 bands were applied but were eventually discarded due to excessive bleeding due to lack of visibility and sclerotherapy was done instead. Following sclerotherapy, an esophageal ulcer developed post-op supposedly due to mucosal involvement during banding.

THE PROBLEM

Current therapies for the management of varices/variceal hemorrhage are multifold. Pharmacological therapy consists of splanchnic vasoconstrictors (vasopressin and analogues, somatostatin and analogues, nonselective β-blockers) and vasodilators (nitrates) which help in reducing the size of varices. [2]

However, acute esophageal variceal bleeding is an intractable complication of portal hypertension. Endoscopic therapies, such as sclerotherapy or endoscopic variceal ligation (EVL), are local therapies that have no effect on either portal flow or resistance. Shunting therapy, either radiological (transjugular intrahepatic portosystemic shunt) or surgical, by bypassing the site of increased resistance, markedly reduces portal pressure by bypassing the site of increased resistance. [2]

Endoscopic injection sclerotherapy (EIS) has been gradually applied to the management of esophageal variceal bleeding since the mid-1970s. EIS performed as the first effective measure proved to be superior to vasoconstrictors or balloon tamponade in the control of acute esophageal variceal bleeding. However, EIS is associated with some complications such as adverse pulmonary and renal effects, esophageal ulceration, stricture, perforation, and death. Complications occur in up to 40% of patients, and treatment-related death in 1% to 2%. [3]

Endoscopic variceal ligation (EVL) was introduced in 1986 and is now considered the treatment of choice for esophageal variceal bleeding. EVL requires placement of an opaque cylinder in front of the endoscope, rubber bands are placed around varices through the flexible endoscope which is used to visualize the vessels. This therapy is affected by the endoscopic vision. Visualization is very important for treatment in a patient with esophageal variceal bleeding, and maybe more impaired when treating by EVL. In theory, this purely mechanical method of obliterating varices should produce no systemic sequelae, and since the quantity of tissue ligated is limited by the design of the device, it should also result in few complications involving the esophageal wall. The incidence of complications, such as pneumonia and esophageal stricture is low. Now EVL has been gradually adopted to substitute for EIS in the treatment of esophageal variceal bleeding. [3]

However re-bleeding rate in both procedures in high, The overall rebleeding rate in the EVL group of these studies was 21.7%, while the rebleeding rate in the EIS group was 33.1%. [3]

NEED STATEMENT

A safer and more effective way to manage actively bleeding esophageal varices (compared to endoscopic banding and endoscopic injection sclerotherapy) to prevent complications such as strictures, ulcers, perforations, and re-bleeding.

FILTERING

Final score = 8

Rank = 9

MARKET POTENTIAL

Epidemiology: The Global prevalence of Cirrhosis ranges between 4.5 -9.5%.[1] Using an average of the two figures and considering an Indian population of 1,300,000,000 we could assume that the probable prevalence of cirrhosis due to any causes is 91,000,000. Gastroesophageal varices are present in approximately 50% of patients with cirrhosis according to guidelines by the American College of Gastroenterology which we could use to infer that 45,500,000 Indians have varices and are at risk of developing active variceal bleeding.[2] The ACG also mentions that variceal hemorrhage occurs at a yearly rate of 5–15%.[2] Using an average of 10% that would mean that there are approximately 4,550,000 cases in any given year in India. Most of these patients would require pharmacological and/or endoscopic management. However re-bleeding rate in these procedures in high, The overall rebleeding rate in the EVL is 21.7%, while the rebleeding rate in the EIS group is 33.1% according to a meta-analysis.[3]

In an 11 center city in India, Mukerjee et. al. found that 1.28% of all patients attending the eleven participating hospitals of India had liver disease. Of these, 33.9% presented with decompensated cirrhosis which speaks of the high prevalence of chronic liver disease in India.[4]

COMPETITIVE LANDSCAPE

CURRENT METHODS OF MANAGING ESOPHAGEAL VARICES [1]

Preventive Measures [2]

- **Screening esophagogastroduodenoscopy (EGD)**: EGD is recommended for the diagnosis of esophageal and gastric varices is recommended when the diagnosis of cirrhosis is made. Size of the of varices and the presence or absence of red signs (red wale marks or red spots) on varices should be noted.
- **Pharmaceutical:** Beta-blockers may be used

Management of Active Variceal bleeding [2]

- **Supportive therapy:** Acute GI hemorrhage in a patient with cirrhosis is an emergency that requires prompt attention with intravascular volume support and blood transfusions, being careful to maintain a hemoglobin of ~8 g/dL
- **Pharmacological therapy**: Somatostatin or its analogues octreotide and vapreotide; terlipressin should be initiated as soon as variceal hemorrhage is suspected and continued for 3–5 days after diagnosis is confirmed.
- **Esophagogastroduodenoscopy (EGD)**: EGD is performed within 12 hours and used to make a diagnosis as well as to treat variceal hemorrhage, either with endoscopic variceal ligation or injection sclerotherapy.
- **Transjugular intrahepatic portosystemic shunt (TIPS):** TIPS is indicated in patients in whom hemorrhage from esophageal varices cannot be controlled or in whom bleeding recurs despite combined pharmacological and endoscopic therapy
- **Balloon tamponade**: This should be used as a temporizing measure (maximum 24 hours) in patients with uncontrollable bleeding for whom a more definitive therapy (e.g., TIPS or endoscopic therapy) is planned

Combination of pharmacological therapy and endoscopic therapy is the most rational approach in the treatment of acute variceal hemorrhage. The use of pharmacological agents with few side effects allows prolonging therapy to 5 days, the period during which the risk of rebleeding is the

highest. A meta-analysis of 8 trials showed that compared to endoscopic therapy alone (sclerotherapy or EVL), endoscopic plus pharmacological (octreotide, somatostatin, vapreotide) therapy improved the initial control of bleeding and 5-day hemostasis without differences in mortality or severe adverse events. Despite urgent endoscopic and/or pharmacological therapy, variceal bleeding cannot be controlled or recurs early in about 10–20% of patients. [2]

ADVANCES IN THE MANAGEMENT OF ESOPHAGEAL VARICEAL MANAGEMENT

Transnasal endoscopy: A multi-center prospective blinded study evaluated transnasal endoscopy with a flexible imaging color enhancement to assess 50 patients. The analysis showed that the technique was at least as good as conventional EGD at detecting varices and patients preferred it to standard EGD and was found to be better tolerated. [5]

Capsule endoscopy: A recent systematic review and structured meta-analysis evaluated the efficacy of capsule endoscopy for screening oesophageal varices. Not considered sensitive enough to screen for varcies compared to the standard EGD. [5]

Transient elastography (TE): TE is a non-invasive technique that can derive a value for tissue stiffness based on the speed of propagation of low-frequency ultrasound. It has been shown to have a high sensitivity for predicting severe portal hypertension but is associated with a large variation in specificity. [5]

Self-expandable, oesophageal covered metal stents (SX-ELLA Danis): These stents offer an alternative to balloon tamponade. These are placed endoscopically, without radiological guidance; they are removable and can be left in place for up to 2 weeks. [5]

Endoscopic ultrasound-guided angiotherapy: Provides real-time visualization that allows improved access and selective obliteration of bleeding varices, is under investigation. [6]

Esophageal venous pressure measurement system: Using optics combined with automatic control and computer real-time image detection technology, a novel noninvasive method of noncontact pressure manometry was developed based on the airflow and laser detection technology in this study. [7]

IDEAL SOLUTION STATEMENT

An effective, safe, quick and affordable solution that can prevent the development of acute variceal hemorrhage or arrest the bleeding without complications including, but not limited to, strictures, ulcers, perforations, and re-bleeding.

NEED CRITERIA

MUST HAVE

- Allows for localization of the varices in 3 dimensions to gauge distention and thickness of walls
- Must be able to act immediately to arrest bleeding or at least within a few hours if combined with pharmacological agents
- Should not cause any mucosal damage, injury or infection in the esophagus
- Should ideally not lead to re-bleeding episodes

NICE TO HAVE

- Should be integrated with the existing gastroenterology set up
- Should be affordable
- Should lead to the eradication of esophageal varices
- Should be applicable for all upper gastrointestinal bleeds including esophageal and gastric varices

REFERENCES:

1. Global Burden Of Liver Disease: A True Burden on Health Sciences and Economies. World Gastroenterology Organization. Accessed 21/8/2018 http://www.worldgastroenterology.org/publications/e-wgn/e-wgn-expert-point-of-view-articles-collection/global-burden-of-liver-disease-a-true-burden-on-health-sciences-and-economies
2. American College of Gastroenterology Guidelines Prevention and Management of Gastroesophageal Varices and Variceal Hemorrhage in Cirrhosis. Accessed 21/8/2018 https://gi.org/guideline/prevention-and-management-of-gastroesophageal-varices-and-variceal-hemorrhage-in-cirrhosis/
3. Dai, Cong, et al. "Endoscopic variceal ligation compared with endoscopic injection sclerotherapy for treatment of esophageal variceal hemorrhage: a meta-analysis." *World Journal of Gastroenterology: WJG* 21.8 (2015): 2534.
4. Mukherjee, Partha S., et al. "Etiology and mode of presentation of chronic liver diseases in India: A multi centric study." *PloS one* 12.10 (2017): e0187033.
5. Haq, Ihteshamul, and Dhiraj Tripathi. "Recent advances in the management of variceal bleeding." *Gastroenterology report*5.2 (2017): 113-126.
6. Ibrahim, Mostafa, Ibrahim Mostafa, and Jacques Devière. "New developments in managing variceal bleeding." *Gastroenterology* 154.7 (2018): 1964-1969.
7. Hu, Chenghuan, et al. "A study on new method of noninvasive esophageal venous pressure measurement based on the airflow and laser detection technology." *Bio-medical materials and engineering* 26.s1 (2015): S413-S422.

10. INCIDENTAL ENTEROTOMY

BACKGROUND

Bowel injury is the third cause of death from a laparoscopic procedure after major vascular injury and anesthesia. Unlike major vascular injuries where the risk and presentation are immediate, many bowel injuries go unrecognized at the time of the procedure. [1]

Overall, bowel injury is a rare complication of laparoscopic surgery. In a recent retrospective analysis of 13 laparoscopic series in general surgery, gynecology, and urology, 266 bowel complications occurred in a total of 205,969 cases. This corresponds to a combined incidence of 0.13%. However, gynecologic procedures accounted for more than 50% and urologic cases for only 0.44% of the total volume of this review. In the urologic literature, slightly higher incidence rates between 0.2% and 1.3% are reported. This fact is most likely attributable to the higher number of complex surgical cases (e.g., laparoscopic radical prostatectomy, laparoscopic RPLND) included in the urologic series. The most commonly injured part of the intestine is the small bowel followed by the colon and the rarely injured stomach. Injuries of the duodenum are the most serious bowel complications of laparoscopic surgery as they are associated with the highest morbidity and mortality rates. [2]

Inadvertent enterotomy potentially is a lethal complication of laparoscopic surgery. Even though no deaths were reported at our institution, death from inadvertent enterotomy is not uncommon. Van der Voort et al found that the mortality rate associated with intestinal injury during laparoscopy was 3.6%. [3]

OBSERVATION

A 50 year male with a renal mass in the left kidney. Initial pneumoperitoneum achieved at the umbilicus. The initial 10-mm trocar is placed under vision at or near the umbilicus. Subsequent trocars placed under vision with the 10-mm laparoscope in the umbilical trocar. A 5- to 12-mm trocar placed lateral to the umbilical port at the edge of the left rectus abdominus muscle. Finally, a third 5-mm trocar is placed midway between the xiphoid and the umbilicus. Mobilization of colon and peritoneum. Plane bluntly dissected by dividing the colorenal ligaments. Duodenum rolled medially to identify the inferior vena cava. Ureter and gonadal vein identified and both the lower pole of the kidney and the renal hilum identified. The lower pole dissection was performed. After ureter and gonadal vein were secured and the inferior pole of the kidney is dissected the renal hilar was dissected. The plane between the adrenal gland and the superior pole of the kidney were bluntly dissected. The ureter was divided. During dissection, the small bowel was damaged with the cautery and the procedure was converted to an open procedure for closure of the bowel injury. The patient remained in the ward without incident before being discharged on post-op day 8

THE PROBLEM

Early recognition is very important for all types of laparoscopic complications, for bowel injuries, however, it is probably most crucial. In this case, a time delay can turn a minor

intraoperative problem into a life-threatening condition. Roughly two out of three intestinal lesions that occur during laparoscopy are only diagnosed postoperatively and up to one out of four patients with delayed presentation of a bowel lesion dies as a result of the complication. [2]

The bowel can basically be harmed by any kind of sharp or blunt instrument. Given the limited field of view inherent to laparoscopic surgery, such an injury can easily go unnoticed.

Entry into the abdomen itself can cause injuries. A large survey of nearly 37,000 gynecologic laparoscopies in the US revealed a 0.16% incidence of bowel injury. 39.8% of vascular and intestinal injuries were caused by the Veress needle, 37.9% by insertion of the primary trocar and 22% by the insertion of the secondary trocar. [1]

Manipulation with instruments outside this field (e.g., during instrument changes) is prone to an inadvertent violation of bowel and other intraabdominal structures. If a lesion cannot be seen directly, free intestinal contents are proof of a bowel laceration. Additionally, the escape of a fecal smell through an opened port valve must lead to a search for a bowel injury. If such a lesion is strongly suspected, the whole bowel has to be inspected meticulously, since moving small bowel loops and the greater omentum tends to hide an intestinal lesion. Even the spontaneous temporary closure of such defects has been reported. Furthermore, the possibility of two or more concomitant injuries has to be taken into consideration. Electrocautery-induced thermal damage is the single most frequent origin of bowel injury during laparoscopic surgery. In a review article, this form accounted for 50% of all bowel lesions. Typically, this injury is missed intraoperatively because of the delayed breakdown of the intestinal wall. So again it is the surgeon's knowledge of possible mechanisms of electrosurgical injury combined with a high index of suspicion throughout the entire procedure that can lead to the detection of as yet invisible bowel lesions. The four mechanisms of electrocautery-induced thermal damage during laparoscopic surgery are inappropriate direct activation of the electrocautery, coupling to another instrument, insulation failure, and capacitive coupling. The typical situation where capacitive coupling can occur is when an insulated active electrode (e.g., monopolar laparoscopic scissors) is introduced through a metal cannula. Through an electrostatic field that is created between the active electrode and the cannula, the current in the electrode can induce a current in the cannula. [2]

NEED STATEMENT

A safer way to allow safe and complete dissection within the abdominal cavity without damaging the bowel such that complications such as peritonitis, sepsis, conversion to open surgery and mortality are avoided.

FILTERING

Final score = 8

Rank = 10

MARKET POTENTIAL

In one of the largest surveys on gynecologic laparoscopies, incidence of bowel injury was found to be 0.16% in 37,000 cases. 39.8% of vascular and intestinal injuries were caused by the Veress needle, 37.9% by insertion of the primary trocar and 22% by the insertion of the secondary trocar. [1]

Out of 18 million minimal access surgeries a year, if we assume that 60% are laparoscopic surgeries of the abdomen and pelvis and using the 0.16% injury rate in literature, it would entail that17,280 of accidental enterotomy occur in a year.

COMPETITIVE LANDSCAPE

CURRENT METHODS USED FOR PREVENTION OF INCIDENTAL ENTEROSTOMY

Prevention of bowel injuries during urologic laparoscopic surgery seems to be difficult since experienced laparoscopic surgeons are reported to cause an equal rate of intraoperative bowel lesions as inexperienced surgeons.

Pre-operative preparations: Routine use of a nasogastric tube to empty the stomach reduces the risk of injury to the stomach. Also, preoperative bowel preparation may reduce inadvertent intestinal trauma by increasing intraperitoneal free space and by facilitating operative maneuvers.

Abdominal entry: Especially for the inexperienced laparoscopic surgeon and assistant, it is advisable to introduce any new instrument under direct visual control in order to prevent inadvertent bowel injury outside the field of view. Likewise, a laparoscopic instrument that is not in use must always be removed from the patient.

Electrothermal trauma: All laparoscopic instruments must be checked for insulation damage prior to their use. Bipolar electrocautery should be used whenever possible and all diathermy must be avoided close to the bowel. Monopolar electrocautery should not be used to take down bowel adhesions. The lowest possible power setting should be used at all times. The electric energy should only be activated when the entire active part of the instrument is visualized and the tip of the instrument is in contact with the target. To prevent duodenal injury in right-sided renal or adrenal procedures, the medial reflection of the duodenum by the Kocher maneuver must be performed using blunt and sharp dissection only. The use of thermal energy must be strictly avoided during this step of the procedure.

Innovative instruments: Devices such as Ligasure, which uses a high-current low-voltage output, or the Harmonic Scalpel, which uses ultrasonic energy for both cutting and coagulation, minimize the spread of thermal energy and thereby may reduce the risk of inadvertent bowel injury.

High-risk patients: Extensive adhesiolysis must be considered an advanced laparoscopic procedure and it should, therefore, remain in the hands of the experienced endoscopic surgeon. Alternatively, in patients with prior abdominal surgery and/or radiation therapy, a retroperitoneoscopic approach may be considered. It has recently been shown that retroperitoneoscopic renal and adrenal surgery can be performed in these patients without

increasing the perioperative morbidity or the convalescence. However, intraoperative orientation can be very difficult in case a surgeon is unfamiliar with retroperitoneoscopy and bowel complications have also been reported with this approach. In a prospective randomized comparison of transperitoneal vs laparoscopic radical nephrectomy in the general patient population, no significant difference in bowel complications was found.

MANAGEMENT OF INCIDENTAL ENTEROSTOMY

Once an intestinal injury is recognized intraoperatively, it can be safely managed laparoscopically in most cases. However, if there is any question as to the integrity of the repair or if the patient had prior radiation therapy, open repair and consultation of a general surgeon should be considered. The laceration should be oversewn in one or two layers if small bowel is involved. Lesions of the colon and the rectum should always be closed in two layers. In simple lesions, it is usually not necessary to resect the injured bowel segment. It is advisable to oversew also small serosal abrasions since these minor lesions can cause major postoperative complications if they are left unattended during the initial laparoscopic procedure. Immediate repair of a bowel injury does not require intestinal diversion even if the rectum is involved, and it usually does not have a significant impact on the postoperative course and the length of hospital stay.

The management of electrothermal injuries of the bowel differs to some extent from the management of simple lacerations. If a thermal injury is caused by bipolar electrocautery, it may be excised and the bowel wall defect may be simply closed as long as the lesion is small in diameter. If more than half of the circumference of the bowel segment is involved, the respective segment needs to be resected and an end-to-end anastomosis should be performed. In injuries that are caused by monopolar electrocautery, on the other hand, the extension of the tissue damage is typically underestimated. Therefore, any monopolar electrothermal lesion necessitates resection and end-to-end anastomosis of the involved bowel segment. Additionally, a safety margin of several centimeters on either side of the injury should be resected before the completion of the end-to-end anastomosis.

Again, all these steps may be performed laparoscopically by the highly experienced endoscopic surgeon. Considering the high morbidity of postoperative intestinal complications, a surgeon who does not feel absolutely confident with advanced laparoscopic bowel surgery is strongly advised to convert to an open procedure or consult a general surgeon. [2]

IDEAL SOLUTION STATEMENT

An accurate, reliable and safe device that allows for the real-time localization and monitoring of the location of the bowel loops and alerts the surgeon in case of a breach especially when the field of surgery has bleeding, fat, scar tissue and adhesions.

NEED CRITERIA

MUST HAVE

- Must be accurate and precise identifying and bowel loops
- Must be very sensitive and specific (no/minimal false positives and false negatives)
- Must not cause damage to the bowel itself
- Must not in any way impede the surgeon's view or compromise the surgical field
- Must alert the surgeon in case of a breach so it can be addressed intra-operatively

NICE TO HAVE

- Must be applicable to other organs where an iatrogenic injury is possible such as the bladder, ureter, common bile duct etc.
- Must be easy to use
- Must be able to identify neural and vascular tissue as well
- Must be portable enough to be shifted to different operation theatres
- Must be affordable

REFERENCES:

1. Krishnakumar, S., and P. Tambe. "Entry complications in laparoscopic surgery." *Journal of gynecological endoscopy and surgery* 1.1 (2009): 4.
2. Muntener, Michael & Romero, Frederico & R. Kavoussi, Louis. (2006). Complications in Laparoscopic Surgery. Emergencies in Urology. 349-363. 10.1007/978-3-540-48605-3_28.
3. van der Voort M. Bowel injury as a complication of laparoscopy. Br J Surg. 2004; 91 (10): 1253–1258