

Outcomes Improvement in Global Surgery
A Case Study of Urethral Stricture Management in Senegal

Maahum Haider

A thesis
submitted in partial fulfillment of the
requirements for the degree of

Master of Public Health

University of Washington

2018

Committee:
Carey Farquhar
Nancy Puttkammer
Hunter Wessells

Program Authorized to Offer Degree:
School of Public Health
Department of Global Health

©Copyright 2018
Maahum Haider

University of Washington

Abstract

Outcomes Improvement in Global Surgery
A Case Study of Urethral Stricture Management in Senegal

Maahum Haider

Chair of the Supervisory Committee:
Carey Farquhar
Department of Global Health

Surgical diseases constitute a significant proportion of the global burden of disease. International surgical organizations are uniquely positioned to provide much needed surgical care while simultaneously empowering local providers to offer the highest quality of care possible within their resource framework. Accomplishing this goal requires a dedicated effort at data collection and outcomes monitoring to promote the practice of evidence-based medicine. This project explores the relationship between a US-based urological NGO – IVUmed, and a large government hospital in Senegal to assess whether this partnership has resulted in improved patient outcomes. Based on direct observation and a retrospective review of the hospital's urological records, we identify areas of concern and offer practical solutions to address the issues.

Introduction

Surgical diseases account for a significant proportion of the global burden of disease. In 2010 alone, 16.9 million people died from conditions requiring surgical care - more than the number who succumbed to HIV, TB and malaria combined.¹⁻³ Despite these estimates, the true prevalence of surgical diseases is still widely unknown in many parts of the world and there is a dearth of literature on surgical management and outcomes from low- and middle-income countries (LMIC). As gaps in surgical care become more widely acknowledged in public health, international health organizations and members of the global health community must prepare to address these needs in a responsible and sustainable way. There is an urgent need to gather data on the epidemiology, current management options, outcomes and unmet needs of surgical diseases. In the absence of centralized or standardized local data collection, we must think critically about the role that international surgical partnerships play when providing surgical care to populations in which essential baseline data is missing.

The last few decades have seen a rise in the number of 'surgical mission trips' consisting of volunteers who donate their time and skills to the technical task of providing surgical care. Well-established groups like Operation Smile originally functioned to fill a necessary gap in care in places where modern surgical services were often non-existent.⁴ However, the development of in-country permanent surgical centers in many parts of the world is leading to a paradigm shift where sustainability and local capacity building are becoming more important.⁴ Over the last 2 decades there has been a growing trend of shifting focus away from disease-specific or 'vertical' programs and towards the much broader goal of strengthening health systems.⁵ This daunting task is made even more difficult by the lack of in-country health data and poor record collection systems in many LMICs. In general, surgical missions thus far have not prioritized data collection, outcomes tracking, or assessing the various factors that affect a patient's outcome outside of the operating room. Without this information, there is no empirical way to assess the impact or cost-effectiveness of surgical trips or to determine how to better allocate resources.

While the lack of data is a considerable barrier to providing quality surgical care, LMIC additionally suffer from poor surgical training in the public sector, infrastructural challenges and the absence of surgical care as part of a national health plan. This is particularly true for sub-specialties like urology, where practitioners often have few options for basic or advanced training and lack the specialized equipment that is commonplace in high-income countries (HIC). As a result, urologic care in many parts of the world is still delivered in archaic forms that have historically high rates of morbidity and mortality.⁶ As of 2010, the Global Burden of Disease (GBD) project estimated that benign urologic conditions accounted for 13.5 million disability-adjusted life years (DALYs), while malignant urologic conditions accounted for almost 200 million DALYs. The World Health Assembly has included surgery and anesthesia as part of universal health coverage and providing surgical services is now a part of the United Nations' post 2016 Sustainable Development Goals.⁷ This sets the stage for urologists who practice global health, to actively participate in the effort to practice evidence-based medicine and apply the same ethical and scientific standards to their international patients as they would at their home institutions.

Urethral Stricture Disease in West Africa

Urethral stricture disease is a benign urologic condition caused by scar tissue in the urethra which, in severe untreated cases can lead to significant morbidity and mortality. In the

US and other HICs, urethral strictures are repaired by urologists who have been trained in reconstructive surgery. Currently, there are no urologic reconstructive fellowships in West Africa. In addition, many patients who live outside of big cities, often seek care with local providers who range from general practitioners to community health workers with no formal medical training. As a result, urethral strictures are often managed initially by providers with no urologic background, and in the best-case scenario, at a hospital without a urologic reconstructive program. Urethral injuries can result from direct injury to the perineum which is more likely with the rise of motorcycle and bike use in developing nations. A 2011 study from Senegal found that male urethral strictures were frequently caused by gonococcal urethritis and gangrenous infections of the genitalia.⁸ There is currently no prevalence data on urethral stricture disease in West Africa, and no outcomes data on surgical management.

This project focuses on urethral stricture disease to explore the relationship between a large government hospital in Dakar, Senegal and a US-based urologic NGO that has been engaging in surgical missions there for the last 10 years. An attempt is made to determine whether the surgical partnership with the NGO has led to any measurable changes in management or patient outcomes. In order to do that, we explore in detail the way urethral strictures present to and are managed at the hospital over the last 11 years. Finally, we aim to use this information to guide further intervention that may empower the local urologists to function more independently, track their own data, and promote sustainable improvements in patient care.

Objectives:

1. To describe the working relationship between IVUmed (a US-based urologic NGO) and the urology department at the Hopital General de Grand Yoff (HOGGY) in Dakar, Senegal as it relates to urethral stricture management.
2. To describe the nature of urethral stricture disease presenting to the HOGGY and how it is managed, including the etiology, pre-operative management, surgical treatment and outcomes.
3. To assess for any quantifiable changes in management or outcomes of urethral stricture disease at the HOGGY after its partnership with IVUmed.
4. To identify areas of actionable change that could be addressed by NGOs like IVUmed and other international surgical organizations to promote sustainable quality improvement in urologic care in low resource settings.

Methods

This study employs both qualitative and quantitative methods to address the above-stated objectives. The study was conducted on-site, over 6 weeks in Dakar Senegal.

Program Description: IVUmed is a US-based non-profit, urologic organization that has been working with international partners in over 30 cities worldwide since 1994. In contrast to most international surgical groups, IVUmed employs a ‘teach-the-teacher’ model. Their mission is to train local providers *on-site* to diagnose and manage complicated urologic diseases according to evidence-based principles that those providers can then impart to their own trainees. Historically, the workshops have been focused on teaching intra-operative surgical skills to the local urologists. There has not yet been a dedicated didactic portion to the workshop that focuses on the medical literature, or peri-operative management. To date there has been no formal program evaluation of IVUmed to quantify the impact they may have had at their partner sites.

Site: The Hopital General de Grand Yoff (HOGGY) in Dakar, Senegal is a government hospital with the largest urology department in West Africa. There are 6 general urologists on staff, none of whom have formal reconstructive training. This study began with a reconstructive workshop held by IVUmed at the HOGGY in July 2017, during which one staff urologist in particular was positioned to assume the role of reconstructionist. He was the primary surgeon working with the IVUmed urologist on urethral stricture cases during the workshop.

Design:

Description of IVUmed's working relationship with the HOGGY

IVUmed first partnered with the HOGGY in 2009. Since that time they have conducted 18 surgical workshops on pediatrics, laparoscopy, oncology, and female and male reconstruction. Their first male reconstructive workshop was held in August 2013 and there have been 4 additional workshops since then. Each workshop is led by 1-2 IVUmed volunteer urologists and occasionally a volunteer anesthesiologist and/or nurse. One staff urologist from the HOGGY is responsible for organizing each workshop, depending on the topic and how relevant it is to their practice. During the course of the workshop however, each IVUmed provider may work with a different staff urologist or resident on every case – limiting the exposure and teaching that any one individual gets.

This study began with observation of a male reconstructive workshop from July 9-14th, 2017. During this period, detailed notes were taken on the cases performed, teaching points, dynamic between visiting and local providers, barriers to effective teaching and challenges to providing safe surgical care. Informal interviews were conducted with the staff urologist who worked with IVUmed and other visiting urologists attending the workshop to get a sense of how the workshops are perceived, whether they change their practice back home, and how they think they could be improved. Once the IVUmed team had left, the host urologist was observed doing a variety of urethral stricture repairs on his own. This time, notes were taken on whether the teaching points from the workshop were being employed, and whether his technical skills seemed to have changed after the workshop. Special attention was paid to any factors that are known in the literature to contribute to poor urethroplasty outcomes, such as tissue handling techniques, type of procedure applied to a particular type of stricture and post-operative care.

Description of the nature of urethral stricture disease presenting to the HOGGY

The quantitative portion of this study consisted of conducting a retrospective review of the surgical logs and medical records with approval from the hospital ethics board at the HOGGY. Unfortunately, clinic records are not electronic and there was no way to track the total number of patients who were seen in clinic for urethral strictures over the 11-year period. Similarly, non-operative management of strictures could only be assessed through the medical records of patients who ultimately underwent surgery. The hospital's electronic surgical log dates back to 1989 and access to this was granted for the study. All of the urologic cases performed between January 1st 2006 and July 31st 2017 were extracted and reviewed. Subsequently, the medical records belonging to all patients who had undergone urethroplasty in that time period were requested. These records were reviewed with a local surgeon who translated the hand-written French into English to allow extraction of the variables listed below. Several medical records had no post-operative follow up recorded and in some cases those

patients were contacted by phone to determine their outcome. Not all patients could be contacted. All data was de-identified and stored in a password protected external hard drive that only the primary author had access to.

Variables of interest:

- 1) Demographics (age, region, comorbidities)
- 2) Etiology of urethral stricture
- 3) Prior treatments for urethral stricture (number, type)
- 4) Nature of urethral stricture (presenting symptoms, number, length, location, recurrence)
- 5) Preoperative diagnostic workup
- 6) Date of surgery and timing from last intervention, if any
- 7) Surgical technique used for reconstruction
- 8) Post-operative course (complications/success/failure/additional interventions)
- 9) Length of follow-up
- 10) Whether IVUmed was involved in the urethroplasty or not

Post-operative success was defined as a minimum of 6 months of follow-up over which there was no need for further intervention and the patient reported satisfaction with his urinary symptoms. Failure was defined as any additional post-operative intervention for the stricture after urethroplasty or patient report of difficulty urinating. The 6-month timeframe was used to determine success because patients were not asked to return for follow-up if they were found to be doing well at their postoperative visit. As a result, the majority of patients who were asymptomatic after surgery, did not return for further follow-up. Outcome was ascertained through chart analysis in the majority of cases. Additionally, 8 patients who had no post-operative outcome documented in the charts were contacted by cell phone to determine if they needed any postoperative interventions or were happy with their urinary symptoms.

Inclusion Criteria: The surgical log was reviewed for all cases relating to male urethral stricture disease between January 1st 2006 and July 31st, 2017 to assess preoperative management and types of cases performed. Statistical analyses performed only on urethroplasty cases since these procedures are the focus of IVUmed's reconstructive workshops. All urethroplasty cases performed on men aged 19 or older between January 1st 2006 and January 31st, 2017 were included for outcomes analysis. Patients with a history of prostate, bladder or urethral cancer were excluded from analysis. Two of IVUmed's latest male reconstructive workshops were held within 6 months of this analysis and as a result, the success of those urethroplasties could not be confirmed. However, if they failed within that timeframe, they were included in the analysis.

Effect of partnering with IVUmed

A combination of qualitative and quantitative data was used to assess how the partnership with IVUmed had changed the urology practice at the HOGGY. The notes and interviews taken during and after the workshop were used as a descriptive tool to assess for any immediate changes in how urethroplasty cases were approached and performed. The data collected from the medical records was used to assess for any changes in urethroplasty outcomes before and after IVUmed started their male reconstructive workshops in 2013.

Statistical Analysis: Standard descriptive statistics for categorical and continuous variables were performed where appropriate. Data analysis was performed on total number of patients operated on *and* total number of urethroplasties performed. All categorical variables were compared using the χ^2 test statistic and binary variables using the Student's t-test. Proportions of successful and failed operations among total cases performed were calculated by year. Procedures with unknown outcomes were excluded from the outcomes analysis. Logistic regression was used to estimate the odds of urethroplasty failure using both crude and multivariable models given IVUmed's involvement, number and type of prior procedures performed, stricture length and location, interval between procedures and surgical technique used. The odds of failure in the multivariable model were calculated relative to the date of IVUmed's first male reconstructive workshop, that is, before and after 8/12/13. Statistical significance was set at $\alpha=0.05$. Statistical analyses were performed in State/SE version 14.2 (StataCorp LLC, College Station, Texas) and R version 3.5.0.

Identifying areas for actionable change

Direct observation of surgery and review of the medical records from the perspective of a urologist, both lead to several clearly identifiable issues that could contribute to the success or failure of a urethroplasty. To combat the avoidable pitfalls, a set of management guidelines were created, based on the urethral stricture guidelines from the American Urological Association. These guidelines were tailored to the resources available at the HOGGY and included only tests and procedures that could be offered at the site. The local urologist who would be taking charge of male reconstruction participated in drafting the guidelines and ensured that they were shared with the other urologists in the department.

Results

Description of IVUmed's working relationship with the HOGGY

During the reconstructive workshop in July 2017, there was one IVUmed urologist working with a staff urologist who was positioned to assume the role of reconstructionist at the HOGGY moving forward. Unlike previous workshops, he was the primary surgeon working with the IVUmed provider on each urethral stricture case. A number of patients had been lined up by the staff urologist in anticipation of the workshop. The day before surgery, they were seen together with the IVUmed provider and the staff urologist. Their records were reviewed and in any case with an incomplete or inadequate preoperative workup, the IVUmed provider reviewed the necessary components of a complete and adequate workup. A total of 20 patients were seen and 7 urethroplasties were performed in 3 days. During surgery, the IVUmed provider guided the staff urologist where necessary and honed in on reconstructive principles that were not included in their general urology training. The dynamic between the two surgeons was collegial and mutually respectful. Notably, some of the key surgical instruments used in reconstructive urology were either missing or in disrepair. The IVUmed provider made a point of using only the available instruments so that the staff urologist could reproduce the same skills and techniques after the workshop.

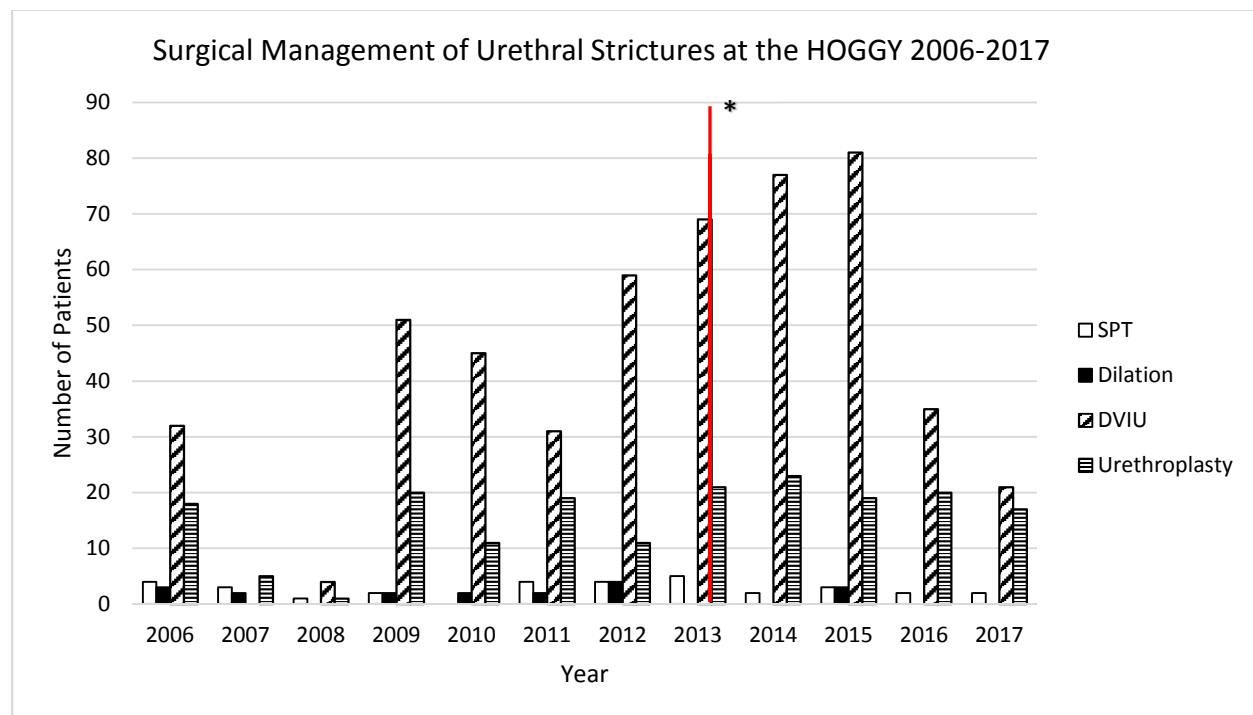
In addition to the primary surgeon working with the IVUmed provider, there were at times 8-15 other visiting urologists from neighboring countries watching the case with the intention of performing the same surgery at their home institutions. Informal, open-ended interviews with several of these providers revealed that they too had no formal reconstructive training and yet were faced with urethral stricture disease on a regular basis. Their experience

with urethroplasty was limited to surgical textbooks, medical conferences and surgical workshops like this where at best, they were able to glimpse parts of the operation over the shoulders of others. Most of the visiting providers said they gleaned something from the workshops that they then employed in their own practice. One provider said the workshops were no more useful than looking at the pictures in a surgical text book. Overall, they generally felt the workshops were helpful. When asked what could be improved, they wished to cover a wider variety of topics and to start the workshops in their own home institutions.

The nature of urethral stricture disease presenting to the HOGGY

Due to the absence of clinic records, the overall number of patients seeking care at the HOGGY for urethral strictures is unknown. Between January 1st 2006 and July 31st 2017, a total of 774 surgical procedures were performed to treat urethral strictures on 569 patients. Of these procedures, there were 539 direct-vision-internal urethrotomies (DVIU), 185 urethroplasties, 32 suprapubic tube placements (SPT) and 18 urethral dilations. Of note, the SPTs and urethral dilations included here were performed in the operating room. Procedures performed in the ER and clinic were not captured. Figure 1 shows a breakdown of the types of surgical interventions performed by year.

Figure 1.



*Start of IVUmed male reconstructive workshops

SPT: Suprapubic Tube, DVIU: Direct Vision Internal Urethrotomy

Over the last 11 years, 115 patients met inclusion criteria for this study and collectively, they underwent 145 urethroplasties. Table 1. shows demographic information on the 115 patients that were included in this study. Patients' educational level and socioeconomic status was not noted in the medical records.

Table 1. Patient Characteristics (N=115)

Variable	N (%)
Age	
<20	2 (1.7%)
20-39	42 (36.5%)
40-59	32 (27.8%)
60-79	36 (31.3%)
>=80	3 (2.6%)
Region of Residence	
Dakar	82 (71.3%)
Other	33 (28.7%)
Documented Comorbidities	
No PMH documented	52 (45.2%)
Diabetes Mellitus	4 (3.5%)
Smoking	3 (2.6%)
Benign prostatic hyperplasia	11 (9.6%)
Bladder Schistosomiasis	4 (3.5%)
Recurrent UTI/Urethritis	8 (7.0%)
Urolithiasis	1 (0.9%)
Renal Insufficiency	3 (2.6%)
Other PMH	38 (33.0%)

UTI: urinary tract infection, PMH: past medical history

Most patients undergoing urethroplasty were young and otherwise healthy. The modal age at the time of surgery was 30. Many patients who presented to the HOGGY had been initially worked up elsewhere and in most cases, had undergone some prior treatment for their stricture. Table 2 lists the proportion of patients who had undergone some prior surgical treatment for their strictures and describes the nature of the intervention.

Table 2. Prior Management of Stricture (N=115)

Variable	Value
Patient has documented prior surgical treatment of urethral stricture, N (%)	
Yes, 1 prior procedure	37 (32.2%)
Yes, 2 or more prior procedures	47 (40.9%)
No	31 (27.0%)
Patient has had prior dilation of urethral stricture, N (%)	
Yes	34 (30.9%)
No	76 (69.1%)
Unknown	5 (4.3%)
Patient has had prior DVIU, N (%)	
Yes	50 (45.5%)
No	60 (54.5%)

Unknown	5 (4.3%)
Patient has had prior Urethroplasty, N (%)	
Yes	39 (33.9%)
No	71 (61.7%)
Unknown	5 (4.3%)

DVIU: Direct Vision Internal Urethrotomy

As a result of having prior intervention, many of the patients who underwent urethroplasty at the HOGGY presented with long, complicated strictures. The most common documented causes of strictures were pelvic fracture urethral injury (PFUI) and infection (26.1% and 24.4% respectively). In most cases, there was no etiology documented in the medical record. The vast majority of strictures were located in the distal urethra (82.6%). A smaller percentage were proximal (13%) and in 4.3% of cases, there was no documentation of stricture location and no accompanying X-rays that could be used to make the determination. Table 3. lists stricture characteristics that could be retrieved from the medical records.

Table 3. Stricture Characteristics at Initial Presentation (N=115)

Variable	N (%)
Etiology of stricture	
PFUI	30 (26.1%)
Post-infectious (urethritis/GU soft tissue infection)	28 (24.4%)
Iatrogenic (prior transurethral intervention)	25 (21.7%)
Unknown	32 (27.8%)
Location of Stricture within Urethra	
Proximal	15 (13%)
Distal	95 (82.6%)
Unknown	5 (4.3%)
Presenting symptoms	
Referred for known history of urethral stricture	41 (35.7%)
Difficulty urinating/complete retention	62 (53.9%)
GU soft tissue infection	9 (7.8%)
Other	3 (2.6%)
Length of stricture (cm), N (%)	
=< 2cm	40 (34.8%)
>2cm	35 (30.4%)
Unknown	40 (34.8%)

PFUI: pelvic fracture urethral injury, GU: genitourinary

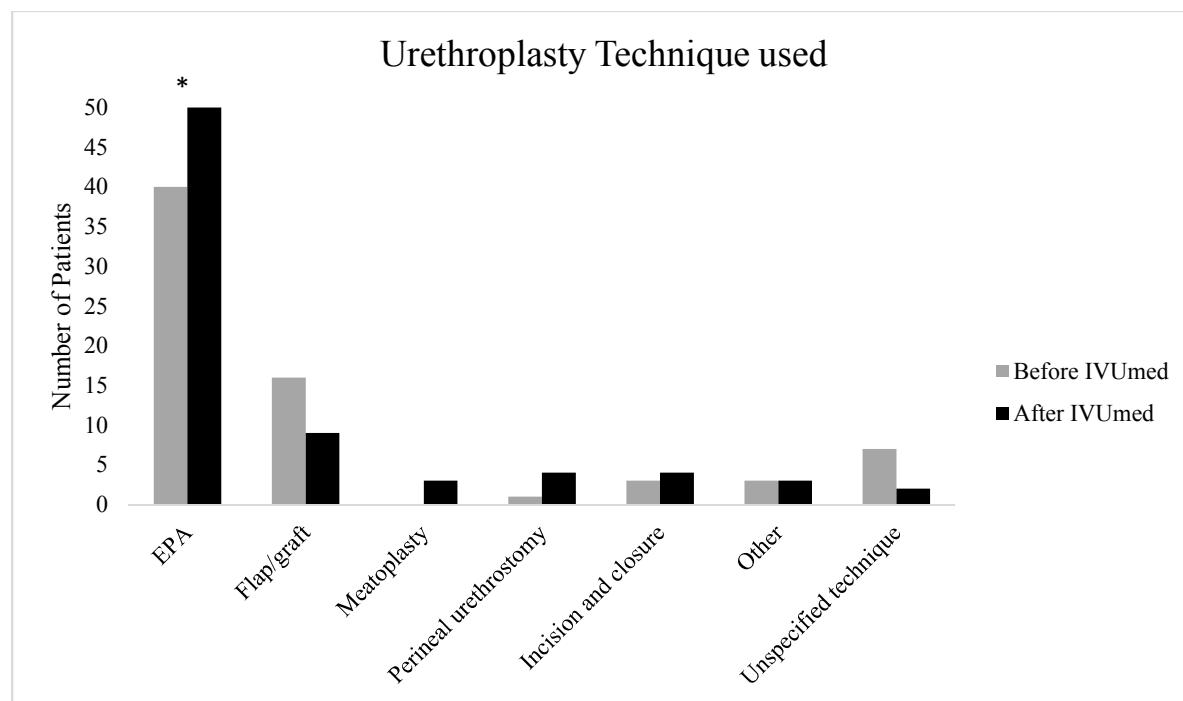
A variety of urethroplasty techniques were employed to treat these strictures. Over the 11-year period reviewed, excision and primary anastomosis (EPA) was the most common urethroplasty technique used (62% of urethroplasties). Seventeen percent of urethroplasties were performed using a flap or graft and the remaining 21% employed some other technique or the technique used was not specified.

Effect of partnering with IVUmed

Increase in number and types of procedures performed

The number and types of urethroplasty techniques used by the HOGGY urologists changed somewhat after IVUmed started its male reconstructive workshops in 2013. A total of 70 urethroplasties were performed on adults in the 7 years before IVUmed's initiation of male reconstructive workshops (an average of 10/year). In the four years since then, 75 adult urethroplasties have been performed (an average of 18.75/year). Seventeen of those urethroplasties were performed with IVUmed providers over the course of 5 workshops. There was a statistically significant increase in the yearly average of EPA urethroplasties from 5.7 to 10 (p value = 0.035) after the reconstructive workshops began. The yearly number of urethroplasties employing a flap or graft decreased slightly after the workshops began but this was not statistically significant. In addition, meatoplasty as a technique was introduced after IVUmed began its workshops. The difference in the numbers of urethroplasties performed using other techniques was not statistically significant. Figure 2 shows the types of procedures performed before and after IVUmed's reconstructive workshops began.

Figure 2. Urethroplasty techniques performed before and after IVUmed (N=145)



EPA: excision and primary anastomosis

*Number of EPA urethroplasties increased from a yearly average of 5.7 to 10 ($p < 0.05$)

Improved success rates

There were 145 urethroplasties performed within the 11-year timeframe. A total of 19 urethroplasties were performed within 6 months of this analysis and 6 of those had failure documented in the chart. These 6 cases were included in the outcomes analysis. The remaining 13 cases were excluded from the analysis as their outcomes could not be confirmed. Of the 132 qualifying urethroplasties, 110 had success or failure documented in the chart. An additional 8

patients were contacted by phone and were able to confirm their outcomes verbally. These 118 patients were included in the final outcomes analysis.

The outcomes after urethroplasties improved significantly after IVUmed's workshops began in 2013. The success rate more than doubled from 12.7% to 29%, leading to a reduction in the failure rate from 87.3% to 71% ($p<0.03$).

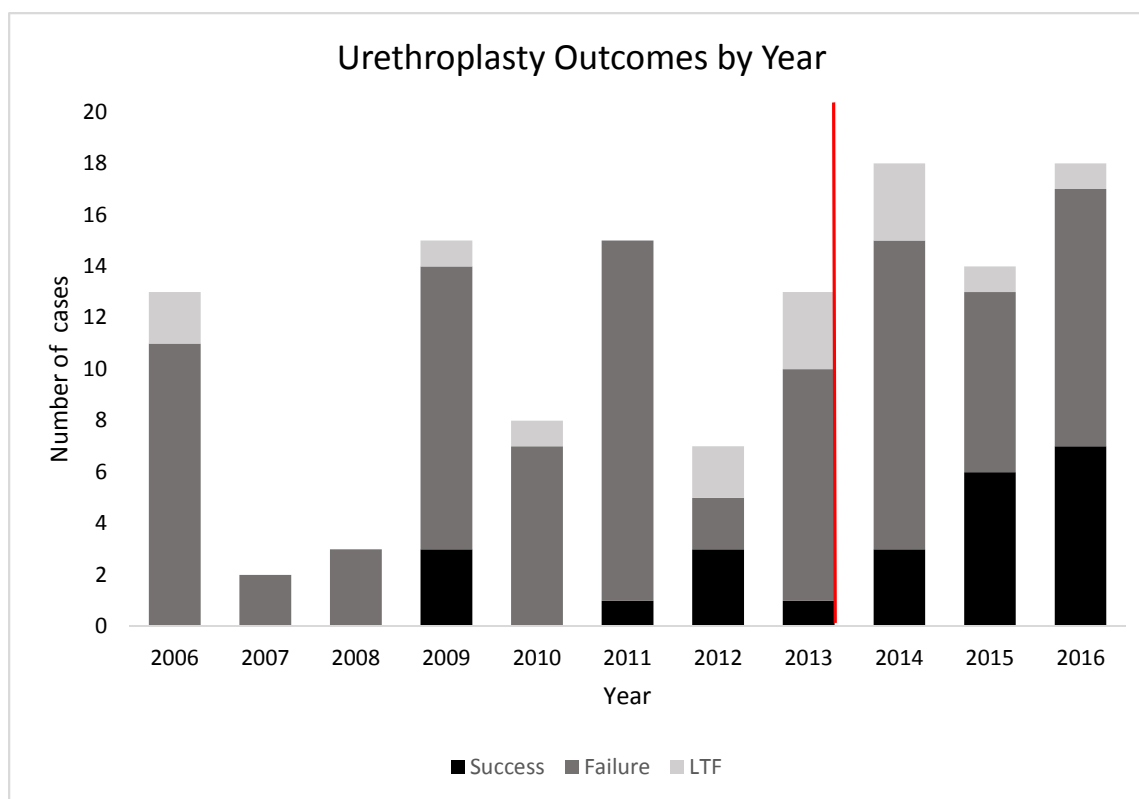
There were a total of 14 patients (7 before and 7 after the workshops) who were lost to follow-up and could not be contacted by phone to determine the outcome of their urethroplasties. A comparison of the group of patients who were lost to follow-up before and after the workshops showed no significant difference in any disease characteristics or types of procedures performed.

We took a more in-depth look at EPA urethroplasties since these were the most common procedures performed before and after IVUmed's involvement. A total of 73 EPA urethroplasties had known outcomes. Of these, 36 were performed before and 37 were performed after 8/12/13. The success rate for EPA urethroplasties also doubled from 16.7% to 35.1% and failure rate in turn decreased from 83.3% to 64.9% but this was not statistically significant ($p=0.07$). The EPA technique accounted for the greatest proportion of successful cases (81%).

Of the 37 EPA urethroplasties performed after IVUmed's involvement, 4 were indicated to have been performed with IVUmed providers. One of these cases was successful, two failed and one was lost-to follow-up. Figure 3 shows the trend in urethroplasty outcomes after IVUmed started male reconstructive workshops (indicated by the red line). There were 19 cases performed in 2017 with less than 6 months of follow-up time, and among these 6 had already presented as failures at the time of data collection. There were 13 cases whose outcomes were yet to be determined.

There was no change in the success rate for procedures using a flap or graft. Success rates for unspecified techniques remained extremely low.

Figure 3. Urethroplasty Outcomes by Year



TBD: to be determined.

Red line indicates start of IVUmed male reconstructive workshops

Factors associated with surgical outcome

Several factors were assessed independently for their relationship to procedure outcome. Due to missing data points in the medical records, the overall number of procedures assessed for each factor varied. On raw analysis, the odds of failure for all urethroplasties were 65% lower after IVUmed's workshops started in 2013, regardless of whether an IVUmed provider personally participated in the case or not ($p=0.05$). Urethroplasties that were performed in the absence of any prior surgical intervention had an 80% lower odds of failure ($p<0.01$). A positive history of prior urethral dilation or DVIU was not associated with a statistically significant difference in outcomes. When the technique used was anything other than EPA or a graft/flap technique, the odds of failure were seven times higher ($p=0.05$). Table 4 shows the odd ratios for procedure failure relative to several predictors.

Table 4. Factors associated with procedure failure (N=118)

Predictor Variables	Subgroup size (N)	Odds of failure	95% CI	P value
Surgery performed after IVUmed reconstructive workshops	118			
No		REF	REF	
Yes, without IVUmed provider		0.38	0.14-0.99	0.05
Yes, with IVUmed provider		0.24	0.04-1.4	0.09

History of prior surgery				
No	118	REF	REF	
Yes, 1 prior		0.88	0.27-3.175	0.85
Yes, 2 or more		0.93	0.27-2.87	0.91
Type of prior surgery				
Urethral dilation	113	1.57	0.61-4.43	0.36
Prior DVIU	113	0.64	0.25-1.58	0.34
Time interval from last procedure to urethroplasty	79			
No prior procedure		REF	REF	
6 months or less		1.14	0.3-4.08	0.84
More than 6 months		0.86	0.24-2.88	0.81
Location of stricture				
Proximal	111	REF	REF	
Bulbar		0.43	0.06-1.76	0.3
Distal		0.74	0.1-4.0	0.74
Length of stricture	77			
Less than 2cm		REF	REF	
2cm or longer		1.9	0.66-6.19	0.24
Urethroplasty technique	117			
EPA		REF	REF	
Flap/graft		1.4	0.45-5.4	0.58
Unspecified/undescribed		8.1	1.55-150	0.05

DVIU: Direct vision internal urethrotomy, EPA: Excision and primary anastomosis

Finally, after removing procedures with missing data points on the variables of interest, we conducted a multivariable analysis on 110 cases. Notably, stricture length was excluded from the multivariable model due to the large number of missing data points. The odds of failure were 66% lower for all urethroplasties after IVUmed's involvement when taking the covariates into account ($p = 0.01$). Importantly, this reduction in failure rate was sustained in cases that were performed without any IVUmed providers but this was not statistically significant. The odds of failure were even lower if an IVUmed provider personally participated in the case, and this difference was statistically significant. The only other statistically significant result was that the odds of failure were 8 times higher when an unspecified technique was used ($p = 0.05$). Table 5 shows the results of the multivariable analysis.

Table 5. Factors associated with urethroplasty failure (N=110)

Predictor Variable	Odds Ratio of failure	95% CI	P-value
Procedure was done after IVUmed reconstructive workshops			
No	REF	REF	
Yes, without an IVUmed provider	0.37	0.11-1.08	0.08
Yes, with an IVUmed provider	0.12	0.02-0.87	0.03
Patient has had prior dilation of urethral stricture			
No	REF	REF	

Yes	1.56	0.39-6.43	0.52
Patient has had prior DVIU			
No	REF	REF	
Yes	0.48	0.1-1.88	0.3
Location of stricture			
Proximal	REF	REF	
Bulbar	0.41	0.06-1.9	0.3
Other	0.28	0.03-1.98	0.22
Urethroplasty technique			
End-to-end Anastomosis	REF	REF	REF
Graft or Flap procedure	1.33	0.3-6.9	0.71
Other	9.45	1.46-190	0.05

DVIU: Direct Vision Internal Urethrotomy

Post-operative course

In the immediate post-operative period, 6.9% of all procedures were complicated by a surgical site infection (SSI). This rate remained unchanged before and after the workshops. The rate of wound breakdown (including fistula formation) decreased significantly however. Before the workshops, 14.3% of urethroplasties were complicated by a wound breakdown or fistula. After the workshops, this rate decreased to 5.5%. The odds of wound breakdown or SSI were 10.4 times higher after a procedure involving a flap or graft than any other technique ($p < 0.01$).

As the failure rates suggest, 81% of patients operated on before August 2013 required some additional intervention after urethroplasty. After the workshops, this fell to 55% ($p < 0.01$). Time to failure ranged from 1 month to 23 months. However, most people who failed, did so within 2 months of urethroplasty. Postoperative interventions for failed procedure included repeat transurethral procedures (dilations and DVIUs), repeat urethroplasties and urethral fistula repairs.

In general, patients' urethral catheters were removed about 1 month after surgery. If they were asymptomatic at their next follow up visit and able to empty their bladders, they were not asked to return for further follow-up. As a result, the typical length of postoperative follow-up was 2 months. However, the total length of follow-up ranged from 1 to 127 months with the longer timeframe consisting mainly of patients who had difficulty urinating and required multiple additional interventions.

Limitations

This study had several limitations. The lack of national data on the prevalence of urethral strictures, common management practices and patient outcomes from urethral stricture management created a lack of context within which to assess the HOGGY's data. Additionally, we were unable to judge the size of the population that sought care for urethral strictures at the HOGGY because we did not have ER and clinic records. As a result, we could not assess non-operative management.

There were several factors identified during the study that could contribute to poor patient outcomes but could not be addressed with management guidelines or by the urologists at the HOGGY. This included late presentation by patients who live in rural areas, mismanagement elsewhere, and high rates of urethritis.

Extracting data from the medical records was fraught with issues because they were hand-written in a foreign language and at times, pertinent records were either missing or damaged. Deciphering hand-writing and translating between languages, could have introduced errors in transcription. Another major limitation was the lack of scheduled follow-up. Several patients had unknown outcomes and their exclusion lowered the power of statistical analysis. Another major limitation of our intervention is that patients are frequently seen by one provider on their clinic visit and operated on by another. This creates a disconnect if the provider seeing the patient in clinic is not well-versed in the management guidelines and fails to complete an adequate workup before the patient arrives in the operating room. The generalizability of this intervention may be limited at institutions where one provider cannot reasonably assume the reconstructive role.

Stricture length was not accounted for on multivariable analysis because of too many missing data points. However, the univariate analysis showed that the outcome of the procedure after IVUmed's involvement was not related to stricture length.

Discussion

The results of this project are very promising while showing clear room for improvement. The fact that urethroplasty outcomes improved after the workshops is even more reassuring given the small number of procedures that were actually performed together with IVUmed providers. Because of the 6 months of follow-up needed to determine success, several cases performed in 2017 were not included in the outcomes analysis. As a result, the time frame of cases included in the outcomes analysis encompassed only 3 IVUmed workshops. As there has been no change in the complexity of disease presenting to the HOGGY or the mismanagement by referring providers, the decrease in failure rates suggests that the surgical decision-making and technical skills taught during the workshops may gradually be manifesting through better patient outcomes that may continue to improve as the number of workshops increases and providers gain more experience. Having said that, the failure rates are still unacceptably high and there are many different factors that may be responsible for that in and outside of the operating room.

Firstly, in an operating room full of observers with a partial view, it is unreasonable to expect that each participant will learn how to independently perform the procedure. Designating a particular provider for each workshop ensures that the principles being taught are reinforced to someone who has actively performed each part of the case and could reproduce those techniques. Ideally, the same provider should engage in multiple workshops until he or she is comfortable not only performing the procedure independently but teaching those techniques to their colleagues and trainees. As a result of this discussion, a provider from the HOGGY has been assigned to assume the role of reconstructionist and will be participating in all subsequent workshops.

There were multiple occasions on which a patient was found to have a worse stricture intra-operatively than was anticipated based on improperly performed X-rays. This sometimes led to an inappropriate surgical technique being applied to certain strictures or surgeons having to perform much more technically challenging procedures than they were prepared for. Because the X-rays are performed by the radiology department, it is important that urologists recognize when an X-ray is incorrectly performed and that the radiologists are shown the proper technique.

We also discussed several non-operative issues that arose from making observations during surgery. Sterile technique was not strictly followed. This was due in part to the paucity

and expense of certain ‘single-use’ instruments which were reused multiple times. These instruments cannot be sterilized in the same way as instruments that are meant to be reused. As a result, the providers acknowledged that they were unsterile but necessary. Sterility was often breached by the many observers in the room trying to get a closer look at the operative field. Small breaches in sterility were so frequent that the providers did not acknowledge them. It stands to reason that breaking sterile technique could have contributed to the postoperative surgical site infection rate but this conclusion cannot be made on the basis of the current data. Many of the surgical instruments were in poor condition. This was due to several factors including poor processing and handling between cases, sharing equipment between other surgical services who may use delicate instruments inappropriately, the expense of replacing instruments, and reports that newly donated instruments were often taken by some providers to their private practice locations.

Postoperative care for urethroplasties can require diligent wound care depending on the technique used. The HOGGY did not have the proper wound care supplies for urethroplasties that employ grafts, which certainly could have contributed to the poor success rate associated with those procedures. Due to the nature of the health care system and the lack of resources in general, patients are not closely attended to by nursing staff and there are few protections for fresh surgical wounds. This increases the risk of dressings coming apart and catheters being dislodged which can seriously hinder wound healing. Finally, after patients have their catheters removed, they are not expected to return. As a result, there is no culture of following up on these patients and making associations to what might improve their surgical outcomes.

The urologist from the HOGGY who worked closely on this project is also the head of the hospital’s health informatics department. He personally was very interested in continuing to collect data and making changes based on the above observations. Some of these changes will be more difficult to make due to the associated cost (buying and maintaining surgical instruments), but others are more easily addressed. For instance, based on this project he has communicated with the head of radiology at the HOGGY and has arranged for a training session on how to properly perform the diagnostic X-rays needed when planning stricture treatment.

Most importantly, we worked together to create a set of management guidelines for urethral strictures that can guide providers on the proper diagnostic workup and selecting the most appropriate surgical technique for the stricture at hand. These guidelines were drawn from the American Urologic Association’s recommendations⁹ which are based on the best available evidence and are included in the appendix. Because the nature of urethral strictures and the resources available at the HOGGY are quite different from what is typically seen in the US, the guidelines were modified and tailored to them. We hope that the guidelines will not only prevent avoidable errors in management but also promote a standard of care that all patients can benefit from. This final concept is important in all low resource surgical settings where management algorithms do not exist and providers have various levels of expertise.

Conclusion

Surgical diseases are a growing concern in global health. Addressing this need responsibly and sustainably requires data collection on etiology, prevalence, management options and gaps in care. International surgical organizations can play an important role in this process as they are uniquely positioned to shape the way care is provided and can monitor the impact they have. Outcomes for urethroplasty improved significantly after only 3 surgical workshops that were aimed at improving both surgical skills and peri-operative management.

Longer follow-up may reveal further improvements in success rates and shed light on areas in need of more attention. International surgical organizations should focus on empowering local providers and promoting the independent practice of safe surgical care rather than fostering a reliance on visiting surgeons. Creating a set of management guidelines in collaboration with local providers can be an invaluable step forward in this process. Ongoing monitoring and evaluation will be needed to assess their impact and identify areas for continued improvement.

References:

1. Shrimpe MG, Bickler SW, Alkire BC, Mock C. Global burden of surgical disease: An estimation from the provider perspective. *Lancet Glob Heal*. 2015;3(S2):S8-S9. doi:10.1016/S2214-109X(14)70384-5
2. Meara JG, Leather AJM, Hagander L, et al. Global Surgery 2030 : evidence and solutions for achieving health , welfare , and economic development. *Lancet*. 2015;386(9993):569-624. doi:10.1016/S0140-6736(15)60160-X
3. Lozano R, Naghavi M, Foreman K, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: A systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012;380(9859):2095-2128. doi:10.1016/S0140-6736(12)61728-0
4. Jones CM, Campbell CA, Magee WP, Ayala R, Mackay DR. The Expanding Role of Education and Research in International Healthcare. *Ann Plast Surg*. 2016. doi:10.1097/SAP.0000000000000721
5. Reich MR, Takemi K. G8 and strengthening of health systems: follow-up to the Toyako summit. *Lancet*. 2009;373(9662):508-515. doi:10.1016/S0140-6736(08)61899-1
6. Boyle P, Maisonneuve P, Steg A. Decrease in mortality from benign prostatic hyperplasia: A major unheralded health triumph. *J Urol*. 1996;155:176–80. [https://doi.org/10.1016/S0022-5347\(01\)66587-X](https://doi.org/10.1016/S0022-5347(01)66587-X).
7. World Health Organization. *Millennium Development goals 2016*. [http://www.who.int/news-room/fact-sheets/detail/millennium-development-goals-\(mdgs\)](http://www.who.int/news-room/fact-sheets/detail/millennium-development-goals-(mdgs))
8. Fall B, Sow Y et al. Etiology and current clinical characteristics of male urethral stricture disease: experience from a public teaching hospital in Senegal. *Int Urol Nephrol*. 2011 Dec;43(4):969-74. doi: 10.1007/s11255-011-9940-y. Epub 2011 Mar 27.
- Roy N. Global surgery: A view from the south. *J Pediatr Surg*. 2017;52(2):203-206. doi:10.1016/j.jpedsurg.2016.11.006
9. Hunter Wessells et al. Male Urethral Stricture. *American Urological Association*. Published 2016. [http://www.auanet.org/guidelines/male-urethral-stricture-\(2016\)](http://www.auanet.org/guidelines/male-urethral-stricture-(2016))

APPENDIX

Management of Urethral Strictures – derived from AUA guidelines on Urethral Strictures 2016 and tailored to the HOGGY.

Initial Diagnosis and Workup:

1. The differential diagnosis of any patient presenting with weak force of stream, incomplete emptying, pain with voiding, recurrent UTIs and rising post-void residual should include urethral stricture.
2. The initial workup of all patients should include a history and physical exam, urinalysis, urine flow parameters, post void residual and assessment of voiding symptoms using a validated questionnaire.

3. Cystoscopy or retrograde urethrogram/voiding cystourethrogram may be used to confirm the diagnosis of a suspected stricture.
4. For strictures requiring urgent treatment (in the event of retention), physicians may place a suprapubic tube, dilate or perform a direct vision internal urethrotomy (DVIU).
5. Strictures that can be managed non-urgently MUST be evaluated to determine length and location. This can be accomplished with a combination of retrograde urethrogram and voiding cystourethrogram to fully evaluate the urethra proximal and distal to the point of narrowing.

Management of Bulbar Strictures measuring less than 2cm in length:

6. First-time treatment may consist of dilation, DVIU or urethroplasty
7. Foley catheter should be removed 72 hours after an uncomplicated dilation or DVIU
8. If the patient is not a candidate for urethroplasty, they may be managed with long-term self-catheterization after DIVU
9. Recurrent anterior strictures after failed dilation or DVIU should be offered urethroplasty instead of repeated transurethral procedures due to the diminishing success rate.
10. Surgeons who do not perform urethroplasties should refer their patients to those with expertise.

Management of Bulbar Strictures measuring 2cm in length or longer:

11. Surgeons should offer urethroplasty as the initial management for long bulbar strictures given the low success rate of dilation and DVIU.
12. Strictures measuring 2 or more centimeters should be reconstructed with the use of grafts/flaps.
13. Excision and end-to-end anastomosis should not be performed due to the risk of penile shortening and curvature.

Management of Anterior Strictures:

14. First-time urethral strictures of the meatus or fossa navicularis can be treated with dilation or meatotomy.
15. Recurrent meatal or fossa strictures should be offered meatotomy.
16. Patients with pendulous penile urethral strictures should be offered urethroplasty because of the high recurrence rate with endoscopic procedures.

Long, multi-segment strictures:

17. Reconstruction can be performed in 1 stage or multiple stages using grafts or pedicled flaps. Buccal mucosa is the preferred tissue for grafting. Pedicled flaps should not involve hair-bearing skin.
18. Perineal urethrostomy is an alternative long-term treatment option to urethroplasty.

Pelvic fracture Urethral Injury (PFUI):

19. PFUI should not be treated endoscopically; instead, delayed urethroplasty should be performed.

Bladder neck contracture:

20. Bladder neck contracture after endoscopic prostate procedures or open prostatectomy may be treated with dilation, transurethral incision (TUIBN), or transurethral resection (TURP).
21. Open reconstruction may be performed for recurrent bladder neck contractures.

Intra-operative guidelines for urethroplasty:

1. ALL instruments and equipment on the operative field, must be sterile.
2. The urethral mucosa should be handled with fine, toothed forceps to prevent any 'crush injury' that could promote re-stricturing.
3. The bulbospongiosus should be handled with broad, non-toothed forceps to prevent bleeding.
4. The urethra should be mobilized 2-3cm proximally and distally to the area of the stricture to allow a tension-free anastomosis.
5. The anastomosis of the urethral mucosal edges should be 'water-tight' to prevent fistula formation.
6. Urethral strictures must be excised or augmented to prevent recurrence. Urethrotomy alone is insufficient.

Urethral biopsy:

7. Biopsy may be performed for suspected lichen sclerosis/BXO, and must be performed for suspected cancer involving the urethra.

Post-operative follow up:

8. Patients should be maintained on oral antibiotics based on the hospital's antibiogram for the duration of urethral catheterization.
9. The urethral should be re-evaluated with a retrograde urethrogram/voiding cystourethrogram 2-3 weeks after surgery on catheter removal. If there is evidence of a leak, the catheter should be replaced.
10. Clinicians should monitor urethral stricture patients with regularly scheduled surveillance visits to identify symptomatic recurrence up to at least 2 years from the time of surgery.