

A Retrospective Study Comparing 8mm and 10mm Fully Covered Self Expanding Metal Stents in Biliary Obstructions

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Abstract:

This is a retrospective, descriptive study on 36 hospitalized patients who received either an 8mm or 10mm fully covered self-expanding metal stent (FCSEMS) in order to treat biliary obstructions. Biliary strictures often lead to biliary obstructions, which can be both malignant and benign, preventing drainage of the bile duct into the intestine. Fully covered self-expanding metal stents have been recently introduced to the field and appear to have the benefits of plastic and metal stents alike. This study compares 8mm and 10mm FCSEMS by observing data in patient demographics, hospital stay, laboratory data, and endoscopist preference. The aforementioned areas of observation were analyzed to recognize points of interest for further investigation. Insight into the unknown differences surrounding the 8mm and 10mm stents is the focus this study begins to investigate. Contribution to the current fund of knowledge regarding the varying sizes (8mm and 10mm) of FCSEMS is the end goal of the study.

Background:

The most common indication for fully covered self-expanding metal stents (FCSEMS) placement is malignant biliary stricture. Bile duct strictures are narrowings of the bile duct that prevent drainage of bile into the intestine. Whether produced by surgical injury to the biliary ducts or resulting inflammatory lesions, strictures may also cause biliary obstruction.¹ Obstruction of biliary flow often leads to obstructive jaundice and elevated liver enzymes. Hepatic effects of biliary obstruction develop more rapidly in complete obstruction as opposed to incomplete obstruction. Hyperbilirubinemia and bilirubinuria appear, and liver enzyme alkaline phosphatase (ALP), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) levels appear elevated.¹ Fully covered self-expanding metal stents have been used in an off-label fashion for the treatment of benign biliary strictures as well.² Patients usually present with obstructive jaundice as the presenting symptom and indication for treatment. These stents may be used as the ultimate treatment, or as a bridge to surgical intervention. The value of FCSEMS use in patients with benign and malignant biliary strictures are many and include: minimally invasive relief of obstructive jaundice, nonsurgical intervention, lower rate of stent obstruction (compared to uncovered metal stents and plastic stents), can remain in place for prolonged periods, and are relatively easy to remove.

Biliary stenting has evolved dramatically since endoscopic placement of the first stent in 1980 for obstructive jaundice.² Stents placed for this diagnosis was proven to be equally effective as surgical drainage. Throughout the years stents have been developed in varying materials and sizes.

Plastic biliary stents are attractive because of their efficacy and affordability. Although easily exchangeable, one of their major drawbacks is the way that they become occluded due to formation of a bacterial biofilm. This leads to recurrent jaundice as well as cholangitis which in turn requires multiple endoscopic retrograde cholangiopancreatography (ERCP) procedures and frequent stent exchange.²

Self-expanding metal stents (uncovered) have a larger diameter than plastic stents and greater strength with maintained flexibility. An advantage of metal stents is their radiopaque quality. They have proven beneficial in the treatment of malignant biliary obstructions, and are more effective than plastic stents for this indication regardless of life-expectancy.³ These stents are more expensive than plastic stents, but are often cost-effective in malignant obstruction due to less frequent interventions. Occlusion with metal stents is still common and occurs because of tissue ingrowth, tumor overgrowth at the ends, mucosal hyperplasia in the stent from inflammation, and/or biliary sludge.² Removing and exchanging metal stents is challenging and is sometimes impossible.

Fully covered self-expanding metal stents were recently introduced in order to prolong stent patency and treat benign biliary disease. Indications for FCSEMS are benign biliary strictures, malignant biliary strictures,

biliary leaks, and post-sphincterotomy bleeding. Although the majority of biliary strictures are malignant, it has been noted that up to 30% can be benign.⁴ Benign biliary strictures include post-operative patients, chronic pancreatitis, benign hilar strictures, and anastomotic strictures after liver transplantation. Malignant biliary stricture, as previously stated, is an indication for FCSEMS. The most common malignancy associated with this complication is pancreatic adenocarcinoma. The value of FCSEMS for this indication is the high technical success rate combined with relatively uncomplicated acute removal when necessary. These stents have been found to have a lower rate of migration and occlusion.² Some studies have shown patency is nearly double that of uncovered metal stents.²

Fully covered self-expanding metal stents may be complicated by stent migration, pancreatitis, cholecystitis, stent occlusion, and cholangitis. Anti-migration designs like anchoring flaps and flared ends have decreased migration rate.² Fully covered self-expanding metal stents appear to be useful in situations that previously required aggressive endoscopic or surgical interventions such as iatrogenic bleeding or perforation.⁵ The use of biliary stents is a constantly evolving intervention to relieve benign and malignant biliary strictures. With regards to choosing to use an 8mm stent versus a 10mm stent in clinical practices, anecdotally it appears that the 8mm is more preferred by the operator. However, the use of either sized stent is entirely experimental and operator based. It is our plan to add to the current fund of knowledge with regard to observational data comparing 8mm and 10mm FCSEMS.

The purpose of this study is to collect demographic as well as pre and post procedure laboratory data regarding the use of FCSEMS with varying diameter (8mm and 10mm) in the treatment of biliary obstruction. Data usage will be descriptive in nature in order to make different comparisons within the patient population, the laboratory data regarding the different diameter stents, and the endoscopists. This is a preliminary study to gather information which will eventually be utilized in an IRB approved protocol to generate hypotheses about the efficacy and outcomes of the use of the two differently sized diameter FCSEMS.

Study aims:

The aim of our study is to collect data regarding 8mm and 10mm FCSEMS in biliary tree obstructions.

Objectives:

The main comparisons to be observed are the following:

Patient demographics for 8mm vs. 10mm stents

Fever/elevated WBC post procedure in 8mm vs 10mm stents

Number of days from procedure to discharge in 8mm vs. 10mm stents

Change between pre and post procedure AST, ALT, and total bilirubin in 8mm vs. 10 mm stents

Endoscopist preferences of 8mm vs 10mm stents

Inclusion criteria and Exclusion Criteria:

Eligibility criteria

Placement of FCSEMS in the biliary tree at LVHN by either Hiral Shah, MD or

Shashin Shah, MD in a 5 year time period (08/2009-08/2014)

Cholangiographic proven biliary obstruction

Age ≥ 18

Exclusion Criteria

Age ≤ 18

Methods:

Using the inclusion and exclusion criteria outlined above, patients were selected who met the criteria. The MRNs were listed in an excel document. Using electronic patient records, data was collected. In the excel document, columns were created to input date of birth (DOB), date of procedure, date of discharge, endoscopist, age, gender, race, height (cm), weight (kg), FCSEMS diameter (8mm or 10mm), FCSEMS length (4,6,8 cm), total bilirubin pre procedure (mg/dL), minimum total bilirubin in 7 days post-procedure (mg/dL), AST pre procedure (U/L), AST minimum in 7 days post-procedure (U/L), ALT pre procedure (U/L), ALT minimum in 7 days post procedure (U/L), Alkaline phosphate pre procedure (U/L), alkaline phosphate minimum in 7 days post procedure (U/L), WBC pre procedure (cells/ μ L), WBC maximum 7 days post procedure (cells/ μ L),

temperature maximum within 7 days of procedure (°F). The categorical data being endoscopist, gender, race, and stent diameter and length were coded as numerical values. The continuous data was entered within the appropriate ranges of the units shown above for each of the different values. Using descriptive data analysis, different variables were compared to form tables and figures for visual representation of the data.

Results:

The patient demographic information obtained for the study’s sample size of 36 was analyzed separately between 8mm and 10mm stents and then together as total stents. The patient demographic data resulted in identifying a mean age of 69.4 years for 8mm stent placement and a mean age of 66.8 years for 10mm stent placement. In addition, the mean weight for 8mm stent placement was 77.8 kg and 87.5 kg for 10mm stent placement. The table discusses other patient characteristics including gender. It was observed that across all stent placement 61.1% of procedures were performed on males. Results also showed 83.3% of all patients were white.

Patient Characteristics				
		8mm (N=18)	10mm (N=18)	Both (N=36)
Age - (yr)	Median	71.5	68.5	70
	Range	33-90	33-94	33-94
Male Sex - no. (%)		12 (66.7)	10 (.56)	22 (61.1)
Race - no. (%)	White	15 (83.3)	15 (83.3)	30 (83.3)
	Black	1 (5.56)	1 (5.56)	2 (5.56)
	Other	1 (5.56)	0 (0)	1 (2.78)
	Unknown	1 (.056)	2 (11.1)	3 (8.33)
Weight- Kg	Median	70.95	85.45	77.5
	Range	60.2-155.9	46.4-124.6	46.4-155.9
Height- cm	Median	170.182	170.182	170.182
	Range	157.484-193.044	157.48-185.424	157.48-193.044
Elevated WBC post procedure (>12 cells/μL) - no. (%)		1(7.14)	4(25)	5(25)

Table 1. Clinical characteristics of patient population separated according to diameter of stent (8mm and 10mm) and both groups together comprising total stents.

The characteristics of patients separated by 8mm and 10mm stents are relatively similar as well as compared with both groups together. The results appear to show little difference in age, gender, height, and weight range. However, an interesting difference appeared with the elevated WBC characteristic. Twenty-five percent of the 10mm stent group were recorded to have an elevated WBC post procedure whereas this only occurred in 7.14% of the 8mm stent patients. In addition to this characteristic, below is a pie chart displaying the percentage of all stents to have a recorded post procedure fever:

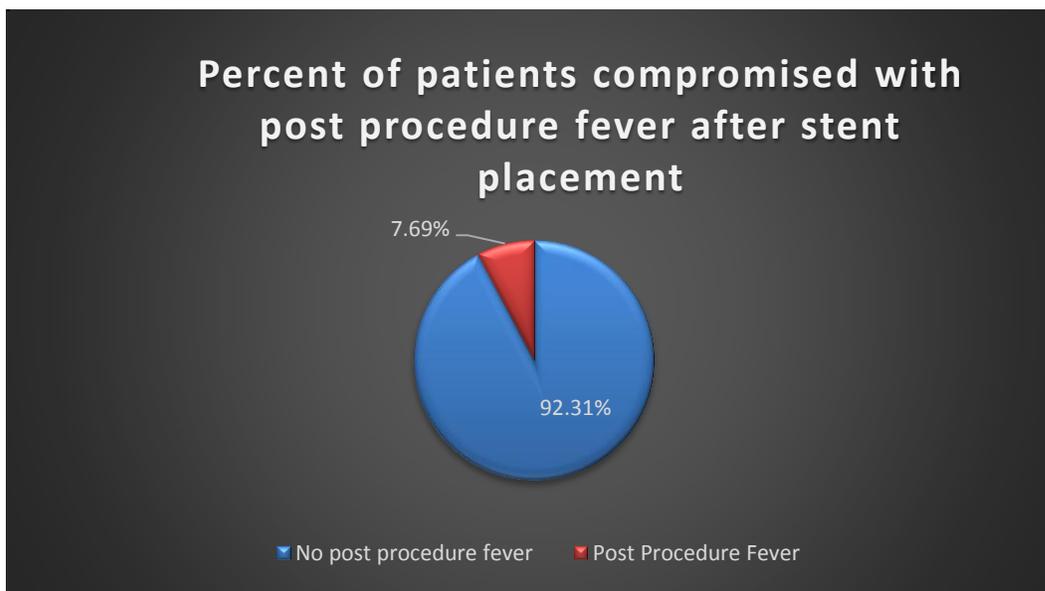


Figure 1. depicting patients sample were have a ≤7 days

Pie chart percent of out of the total size of 36, who recorded to fever (anytime post

procedure).

The results of the pie chart are consistent with the data that resulted in only 2 incidences of recorded post procedure fevers in patients after stent placement; one of the patients received an 8mm stent and the other received a 10mm stent making separation between the two stent sizes and correlation with a post procedure fever insignificant to display. Continuing with patient demographic data, an analysis was performed to view the incidence of 8mm and 10mm placement by age intervals to investigate if a certain age group was more associated with one size stent than the other.

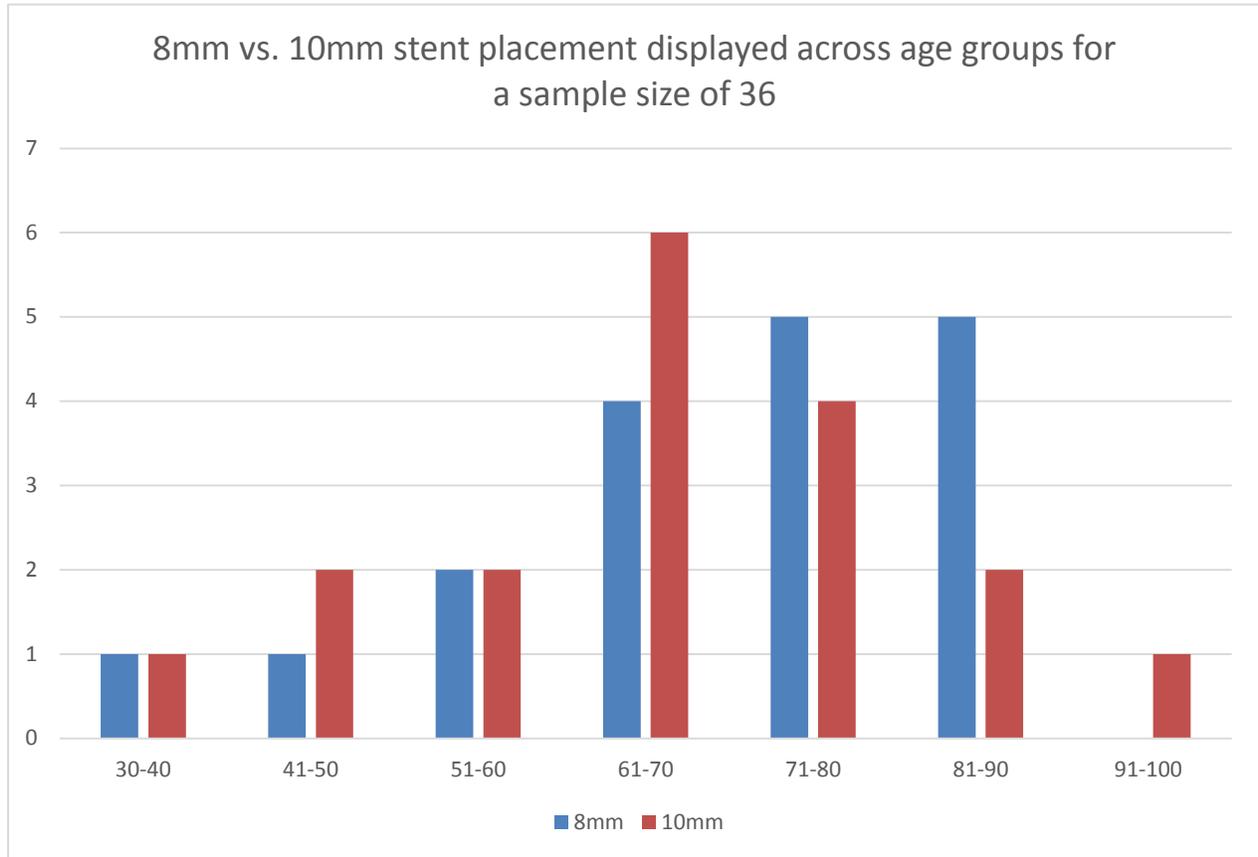


Figure 2. Double bar graph illustrating the number of stents placed in each age group using the range of 33-94 (from Table 1) to determine intervals.

The distribution of 8mm and 10mm stents between the age groupings are fairly similar. There are minute differences in the 61-70 year old group of 2 patients in favor of 10mm stent and 81-90 year old group of 3 patients in favor of 8mm stent.

The mean time from procedure to discharge for the two stent sizes was investigated. The results observed that the 8mm stent placement had a mean hospital stay of 2.44 days with a standard deviation of 0.44 compared with the 10mm stent placement which had a mean hospital stay of 1.83 days with a standard deviation of 0.53.

The AST, ALT, and total bilirubin (TB) levels were monitored pre procedure and post procedure to observe if there was a noticeable correlation between stent size and success in improving laboratory results. The graph below summarizes the findings. The calculated percent changes of each laboratory test showed a greater positive change in the patients that received an 8mm stent although only by a close margin from the 10mm stent.

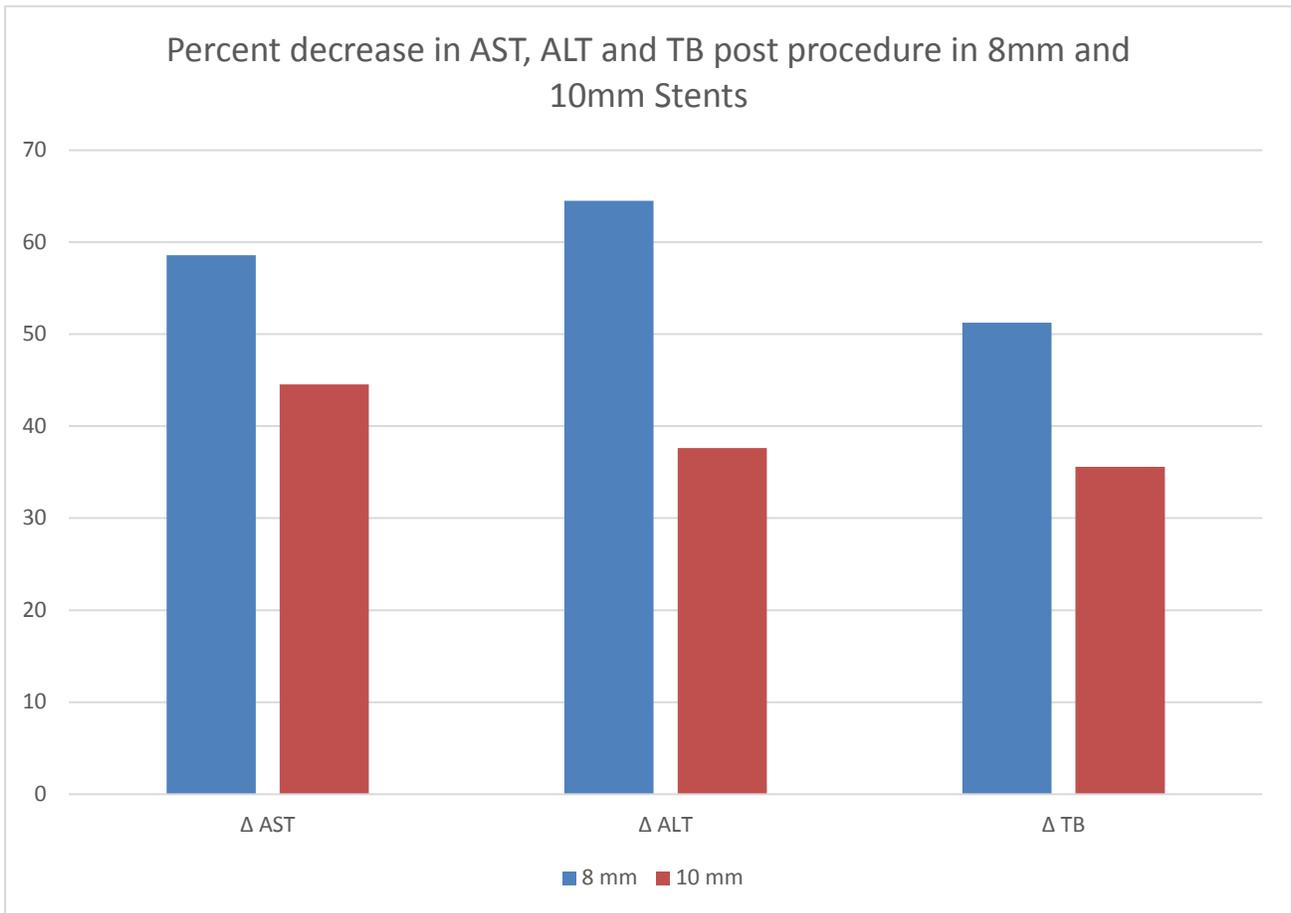


Figure 3. Comparison of 8mm and 10mm stents presented as the percent change in AST, ALT, and TB between pre procedure and the lowest value of each test in 7 days post procedure.

Finally, endoscopist preference was an aspect that we thought may have influenced the occurrence of 8mm stent compared with 10mm stent usage in our patient population. Below are two pie graphs, the first depicting Dr. Hiral Shah’s procedures and the second depicting Dr. Shashin Shah’s procedures. Each chart shows the percent of 8mm and percent of 10mm stents used for the specific endoscopist’s sample size of patients.

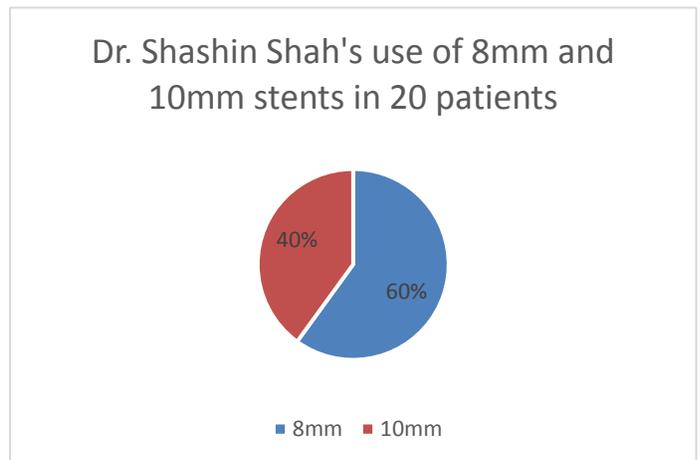
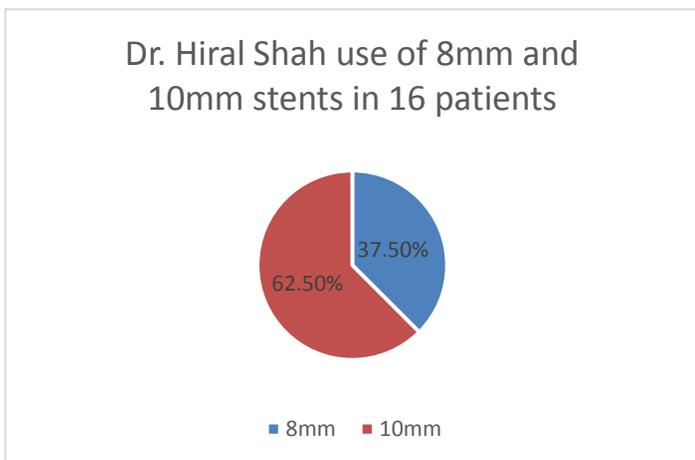


Figure 4. A) Left, displays Dr. Hiral Shah’s procedures delineating 8mm and 10mm stent usage in a population of 16 patients. B) Right, shows Dr. Shashin Shah’s procedures delineating 8mm and 10mm stent usage in a population of 20 patients.

The results of endoscopist preference showed Dr. Hiral Shah placed 10mm stent (62.5%) more often and

Dr. Shashin Shah placed 8mm stents (60%) more often.

Discussion:

Because this study is descriptive in nature, conclusions cannot be drawn. However, observations have led to points of interest for further research to be undertaken. In demographic data, 61% of the patients in the study were of the male gender. This raised the question of whether biliary obstructions are less common in females. Secondly, with 83.3% of the patients being white, the question of biliary disease being more prevalent in whites than people of other races was brought to attention. Additionally, only two procedures resulted in patients with recorded post procedure fevers out of 36 patients. The low incidence of fevers may perhaps be attributed to the quality of the FCSEMS. This would have to be further researched and compared to the other biliary stent types in order to gain evidence for any true conclusions to be made. Although age and stent size appeared essentially equivocal in this study, the question of a correlation between age and stent size may aid in explaining the reasoning for using an 8mm over a 10mm stent and vice versa.

The procedure to discharge from hospital observations for 8mm and 10mm stents are of interest for the quality improvement of the Lehigh Valley Hospital. If a patient recovers quickly and the stent functions to solve the problem equivalently it may be beneficial to implement the use of a certain size stent to decrease hospital stay time, improve patient satisfaction and reduce healthcare expenditure. This study showed shorter average patient hospital stays for the 8mm stent. Hospital stay is an important marker for further research, as certain interventions may decrease time patients spend in the hospital barring complications.

In this descriptive study it appears the 8mm stent performed better in improving laboratory data of the patients post procedure. The 8mm stent had higher percentages of improvement in all three tests that were monitored: AST, ALT, and total bilirubin when compared with the 10mm. This however may be related to patient confounders like 8mm stent being placed in "sicker" patients at baseline, differing reasons for stent placement, and truncated lab evaluation in patients receiving 10mm stents because of clinical symptom resolution. Whether this is a significant finding requires further research to determine.

Endoscopist preference seems to be a more subjective topic. Dr. Hiral Shah appeared to favor using the 10mm stent, utilizing it 62.5% of the time in 10 out of 16 of his patients in the study. On the contrary, Dr. Shashin Shah seemed to prefer using the 8mm stent which he used in 12 out of 20 (60%) procedures recorded for this study. Further study utilizing a survey of endoscopist may explain why one size stent is used over the other, or if the results were coincidental due to the small amount of patients in the sample size. The description for procedure indications could explain the choice to use the 8mm versus the 10mm stent, but was not available in this study.

This study described multiple preliminary observations to be further researched. However, there were numerous limitations of the study worth noting. The descriptive nature of the study restrained the ability to draw conclusions because hypotheses were not identified from the start; there was nothing to accept or reject. In addition, the data collection and demographics were limited in terms of specifics on the patient procedures and conditions which may have impacted the choice of stent size. This could have potentially given us more knowledge to better explain and interpret our observations. If more time was allotted for data collection, there certainly could have been more observable findings. The sample size of patients was relatively small making it difficult to differentiate whether observations were coincidence or worth further investigation. The variation between laboratory improvements was extremely variable leading to wide ranges in change. Although improvements in AST, ALT, and TB may be markers of relieved obstruction, they are not necessarily markers that are reliable for documenting overall clinical outcomes.

The data collection will continue and although this is only a descriptive study, the data is a part of a larger IRB approved protocol to further evaluate the difference between 8mm and 10mm biliary stents. It is our hope that this descriptive study has started the conversation about the different FCSEMS sizes (8mm and 10mm). Contribution to the public fund of knowledge to better define, if there is found to be a difference between the two sized FCSEMS, continues to be the goal of our work.

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Comments:

Mentor: Hiral Shah, MD and guidance from Patrick Hickey, DO