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Research Article

Biliary Drainage Before Pancreaticoduodenectomy: A Comparison of Outcomes between Plastic and Metallic Biliary Stent: Eight-Year Experience from an Oncology Center

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Abstract

Objective: Preoperative biliary drainage (PBD) prior to pancreaticoduodenectomy (PD) has limited, but definite indications. Patients are often referred to high volume centers after PBD. This study seeks to compare the magnitude of complications between different PBD modalities (Plastic and SEMS) in patients undergoing PD at our oncology center.

Material and Methods: The Electronic Medical Records of the patients who had undergone PD between August 2011 and May 2019 were retrospectively analyzed. Chi-square and Mann-Whitney U test were used to test for statistically significant difference between categorical and nonparametric continuous variables respectively.

Results: Between August 2011 to May 2019, 167 patients with mean age of 57 years (117 males) underwent PD. PBD was performed in 64% patients with majority (83, 78%) done outside. The plastic stent (PS=74, 89%) was commonest in this group and three (4%) had self-expanding metal stents (SEMS). In our hospital, three fourth PBD was done with SEMS. There was no statistically significant difference of median pre-stenting serum bilirubin (p=0.5) between us and other centers. In pre-operative waiting period 25% patients experienced stent related complications,19 (24.6%) in the PS group and three (14.8%) in SEMS (p=0.29), commonest being cholangitis (n=23,85%). The median interval between PBD and complications was 29 days (range 0-101). Apart from post operative surgical site infection PS and SEMS group did not differ in peri and post operative outcomes.

Conclusion: Plastic stent continues to be the popular modality of PBD in low-income countries. If surgery is not delayed after PBD in our experience PS seemed to perform equally effectively.

Introduction

Justification of preoperative biliary drainage (PBD) has long been debated in field of hepato-pancreatico - bilary surgery. While few studies claim that this improves the physiological imbalance resulting from cholestasis [1-4] and thereby outcome, majority of randomized controlled trials and other studies , systematic review and meta-analysis suggest that routine PBD does not improve patient outcome rather they are associated with more serious adverse events in patients undergoing pancreaticoduodenectomy (PD) [5-17]. Guidelines also discourage the routine practice of preoperative biliary drainage [18,19].

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However, there are certain situations where preoperative drainage become imperative such as presence of cholangitis, coagulopathy, need for pre-operative optimization, neoadjuvant chemotherapy and long waiting time at high volume centers [20,21] In reality, the practice of PBD cannot be completely done away with. An RCT published in 2010 from Netherland aptly pointed out that the majority of complications resulting from PBD are related to the drainage modality itself and occur in the waiting period for surgery while surgery specific complications are largely comparable [5]. The Plastic biliary stents (PS) which are of small caliber are known to get blocked or displaced, resulting in dysfunction and cholangitis requiring multiple interventions [3]. On the other hand, the metal stents (SEMS) which were initially placed in palliative setting and some benign conditions are of large caliber and less prone to migration and blockage [22,23]. So there has been a heightened interest in use of SEMS in preoperative biliary drainage before PD. This initially was in form of few case series and cohort studies [3,21,24-28]. Later prospective cohort study, RCT and meta-analysis also demonstrated its safety and efficacy [29-32]. Some of these studies claimed clear superiority of SEMS over PS while others failed to show any difference [33,34]. Most of the studies and the guidelines advocating the use of SEMS in preoperative setting are from the western centers where health resources are in abundance. The SEMS is far more costly than PS making the latter still preferred modality in countries like India. Before we adapt to the western practice of using SEMS, we need concrete evidence that use of SEMS results in meaningful improvement in clinical outcome without increasing the cost exorbitantly. Our retrospective analysis is an effort towards this.

Materials and Methods

Our tertiary care oncology setup acts as one of the referral centers in Eastern India and its HPB unit performs average twenty pancreaticoduodenal resections in a year. This study consisted of patients who had undergone PD in Tata Medical Centre (TMC) between August 2011 and May 2019.

The outpatient and inpatient data entered in the hospital electronic medical records were collected and managed using REDCap [35] electronic data capture tools hosted at TMC Kolkata. Algorithm was run on the REDcap using key words "surgical procedure planned" and "surgical procedure performed" for above time period. The filter was set as "Pancreatectomy- Whipple's" or "Pancreatectomy-Pylorus preserving pancreaticoduodenectomy (PPPD)". All patients who were scheduled for PD resection between August 2011 and may 2019 were considered for inclusion. Patient who were initially planned for the surgery but did not undergo PD were excluded.

We retrieved following data of the eligible patients from the REDCap: age, sex, type of pathology, pre drainage bilirubin level, date and place of PBD, type drainage (ERCP, percutaneous, nasobiliary) and nature of stent used (plastic or SEMS). We also retrieved dates of stent related event, type of event, how they were managed, date of surgery, type of operation performed, estimated blood loss (as recorded in surgical notes), post op complications, length of admission and any readmissions within 30 and 60 days or mortality. Only complications that were considered for analysis are bleeding, clinically significant post op pancreatic fistula (POPF B/C), clinically significant delayed gastric emptying (DGE B/C), superficial and deep surgical site infection (SSI), sepsis, chyle leak and bile leak. For any missing data on REDCap the patient's electronic medical record was carefully reviewed and information gap was duly acknowledged.

The data was analyzed using Microsoft Excel® and online statistical software (Medcal, Graphad). Important variables that were taken into considerations for outcome analysis are pre-drainage bilirubin, place and modality of biliary drainage performed, occurrence and timing of stent related events and complications and their management, waiting period for surgery after PBD. Primary outcome was occurrence of stent related events and odds ratio was calculated to judge superiority of one PBD method over other. Operative data that were analyzed included type of operation, duration of surgery and intraoperative blood loss. The latter two parameters acted as surrogate for operative difficulty presumed to be caused by presence of stent. The post operative outcome was assessed based on complications associated with PD such as postoperative pancreatic fistula, delayed gastric emptying, post operative bleeding, occurrence of surgical site infection, chyle or bile leak and sixty-day mortality. Post operative length of stay and readmissions (30 and 60 day) were also analyzed. These were the secondary outcomes of the analysis. We only compared the patients who either had PS or SEMS before PD outcome analysis.

Continuous data was represented as median (along with range and IQR). Chi-square and Mann-Whitney U test were used to test for statistically significant difference between categorical and continuous variables respectively. In case of number of less than five in any categorical variable Fischer's exact test was used. P value less than 0.5 was considered significant.

Given retrospective nature of the analysis our study received an ethical waiver from the institutional review board.

Results

From August 2011 to May 2019 total 167 patients underwent PD at our hospital. seventy six percent (140) underwent classical Whipple procedure and rest (24%, 27) underwent pylorus preserving resection. Median age of the patients was 60 years (IQR 55-66) with 117 males and 50 females (Table 1). Etiology-wise majority had pathology of Ampulla of Vater (AoV= 98, 58%) while 12% had lower bile duct tumor (LBDC=21). Pancreatic and duodenal pathology were present in 24% (n=41) and 4% (n=7 including one GIST) respectively. Thirty six percent patients (n=60) were operated without any PBD (AoV= 31, LBDC= 5, Pancreas= 18 and duodenum= 6). A total of 83 patients (50%) were referred to our center after having had PBD and only 24 (14%) were drained at our institute. Plastic stents were placed in 77 Patients (74 referrals and 3 at our institute, 72%) and SEMS in 21 patients (18 were places at out center, 19.6%). One patient had nasobiliary drainage (NBD) before coming to our center which was later changed to PS. Eight had Percutaneous transhepatic biliary drainage (PTBD=7%, 5 referrals) insertion as endoscopic access failed. While PS was the commonest modality in referred patients (83%) SEMS was the preferred modality (75%) at out setup. Overall, 36% had no drainage, 46% were drained with PS (n=77) and SEMS (n=21) was placed in 12% of cases.

The PS and SEMS groups were comparable (Table 1) in terms of age, gender distribution and pre-drainage median bilirubin level (PS group: 11.95 mg/dl, 7.4-17.4; data available in 38/77 patients and SEMS: 12.99 mg/dl, IQR=9.4-16.8; data available in 19/21 patients). The pre stenting bilirubin level was lower for the referred cases (Median11.80 mg/dl, IQR= 7.90-15.50; data available in 41/83 patients) than those drained at our center (Median15 mg/dl, IQR= 9.5-19.3; data available in 23/24 patients). However, this difference was not statistically significant. Interestingly, 67% (43/64) patients were found to have had PBD at bilirubin level lower than 15 mg/dl. At our set up this figure was 52% (12/23) compared to 75% (31/41) for the referred cases (Table 2).

Table 1. *Comparison of Demographic parameters, pathology, time to event parameters [Median (range*, IQR)]*

No PBD (60)$		PS (77)$	SEMS (21)$	P## (PS vs SEMS)
Median Age in years (range*)	60 (32-76)	57 (21-73)	58 (34-75)	0.94
M:F (117:50)#	47:13	51:26	14:7	
Median pre drainage bilirubin level in mg/dl unit (range*, IOR)	4 (n=51) (0.3-19.4, 6.78)	11.95 (n=38) (1.2-48, 9.97)	12.99 (n=19) (2-30.3, 7.31)	0.63
Location of pathology				
AoV	31	48	14	NA
LBD	5	16	0	
Pancreas	18	12	7	
Duodenum	5	1	0	
Time to event ** in days: Median (range*, IQR)	-	33 (n=18) (9-101, 32)	-	NA
Time to surgery days: Median (range*, IQR)	-	42 (n=67) (7-126, 24)	22 (14-101, 17)	<0.0001

IQR- Interquartile range, PBD- pre operative biliary drainage, PS – Plastic stent, SEMS- self expanding metal stent, AoV- ampulla of Vater, LBD- lower bile duct. NA- not applicable.

** range- minimum- maximum, $ Eight patients had percutaneous (Five males) and one patient (Female) had naso biliary drainage (NBD). Total number of patients without PBD(60), PS (77) and SEMS(21) is 158. # All patients including no drainage, PS, SEMS, percutaneous and NBD. **Time to event- days from date of drainage to date of presentation with stent related complications (bleeding, cholangitis, dysfunction, pancreatitis). ##- Mann Whitney U test*

In our case series a total of 27 patients (25%) experienced PBD related events or complications while awaiting surgery. This includes 23 cases of cholangitis (21%), two cases (one PS and one NBD) of stent dysfunction (2%) and one each of stent related pancreatitis (PS) and bleeding (associated with SEMS). Almost three fourth of cholangitis (17, 74%) occurred in PS group while SEMS and PTBD were responsible for 8.5% (n=2) and 17.5% (n=4) cases respectively. Overall incidence of cholangitis for PS, SEMS and PTBD were 22% (17/77), 9.5% (2/21) and 50% (4/8) respectively. Though the incidence of cholangitis was almost double in PS group as opposed to SEMS this was not statistically significant (OR 2.69 95% CI 0.56-12.72, p=0.21).

Similarly, referred and our own cases were comparable (OR 1.0595% CI 0.34-3.2, p=0.92). Median time to the stent related event in PS group was 33 days (IQR=25-57). As only three patients in SESM had any event comparison was not possible.

Table 2. *Comparison of pre drainage bilirubin level (mg/dl)*

Pre stent bilirubin (mg/dl)	Median	IQR	Range**
NO PBD (Data available in 51/60 cases)	4	6.78	0.3 to 19.4
PBD (Data available in 64/107 case)	12.4	8.45	1.2 to 41 . 67% (n=43) patients were stented at or below 15 mg/dl
PBD at TMC (Data available in 23/24 case)	15	9.81	2 to 30.3. 52% (n=12) patients were stented at or below 15mg/dl
PBD at other centers (Data available in 41/83 case)	11.8	7.57	1.2 to 41. 75% (n=31) patients were stented at or below 15 mg/dl

*** Range- minimum to maximum*

PBD- pre operative biliary drainage, TMC- Tata Medical Center

Table 3. *Comparison of various pathological subgroups for pre intervention bilirubin level, stent related events, time to surgery [data represented in Median (range** and IQR)]*

AoV (67)		LBDC (16)	Pancreas (23)	p$
Pre intervention bilirubin in mg/dl unit: Median (range**, IQR)	11.9 (1.2-41, 8.45)	11 (3.3-24, 13.6)	12.9 (3-25.6, 9.9)	Not significant
Events	12	7	8	
Bilirubin at the time of the event (mg/dl): Median (range**, IQR)	14.8 (4.1-31.3, 16)	-	16.1 (3-25.6,15.7)	
Time to event# (days)	26 (7-88, 49)	32 (28-101, 23)	28 (0-57, 29)	
Time to surgery in presence of event#(days)	41 (21-126, 19)	46 (28-113, 41)	48 (27-91, 34)	
Time to surgery when no event# (days)	36 (14-101, 25)	41 (26-50, 11)	27 (27-88, 38)	

*** Range- minimum to maximum, #Time to event- days from date of drainage to date of presentation with stent related complications (bleeding, cholangitis, dysfunction, pancreatitis), $- Mann Whitney U test*

AoV- Ampulla of Vater, LBDC- Lower bile duct cancer/tumour

Median interval to surgery was significantly lower in SEMS group (22 days, IQR= 18-35) as opposed to PS (42 days, IQR= 32-65, p<0.0001, data available for 67 patients) irrespective of events. In plastic stent group occurrence of event did not significantly delay the interval to surgery (41 days, IQR= 31-53 when no event versus 46 days, IQR=

31-64 with event, p=0.2). In our series type of pathology (Incidence of complications: AoV=18%, lower bile duct= 43%, pancreas=34%, p=0.052) or median pre-PBD drainage bilirubin (12.1 mg/dl versus 13.9 mg/dl, p=0.27) was neither shown to significantly affect the incidence of stent related events nor alter the wait period for surgery (Table 3). Median wait period for surgery was 37 days (IQR= 24-50) and 42 days (IQR= 31-56) respectively in absence or presence of complications (Table 4). Of the 23 cholangitis, 34% (n=8) could be managed with parenteral antibiotics which includes two SEMS related cholangitis. One fourth (n=6) had their PS replaced with SEMS another two had PS (8%) including one who had initial NBD. In two patients PS was removed and no further drainage was done. Two patients had multiple endoscopic interventions and one patient each (4%) underwent non-therapeutic endoscopy and percutaneous biliary drainage as salvage procedure.

Table 4. *Comparison of pre intervention bilirubin# level between groups experiencing and not experiencing events*

	Group with no event (49)#	Group with events (15)#	p$
Median bilirubin in mg/dl (range*,IQR)	12.1 (1.2-41, 8)	13.9(3-31.3, 16)	0.27
Median wait period for surgery in days (range*, IQR)	37(7-101, 26)	42(21-126, 25)	0.052

*# numerator for the analysis includes only the patients with known pre drainage bilirubin level, * Range- minimum to maximum, $- Mann Whitney U test*

This accounted for a reintervention rate of close to 17% (13 out of 77 PS) as compared to approximately 5% (one out of 21 SEMS).

Total 62 patients (37%) were operated without any stent in their system while 66 had PS (39%), 31 (19%) and 9 (5%) patients had SEMS and PTBD respectively when they underwent surgery.

We compared the two groups (PS and SEMS) in terms of surgical outcome (table 5). The median per operative blood loss (500 ml vs 570 ml) were similar so was the operating time (480 versus 440 min) and this did not differ much from the patients who had no drainage either. The median length of post operative stay was 14 days in both groups with 7.7% and 9.5% 30-day readmission rate. The overall sixty-day readmission rates were also comparable (11.7% for PS and 14% for SEMS). The PBD group in general had higher thirty and

sixty-day readmission rates than those operated up front (3.3% and 8.3%). About one fifth patients in both groups had post op hospital stay exceeding three weeks. Comparison of both PS and SEMS group in terms of post operative complications did not yield any statistically significant difference except SSI rate (4.7% in SEMS group vs 30% in PS group). Our case series had 5.9% sixty-day mortality rate. There were four deaths in PS (5.1%) group and six (10%) in undrained groups. No patient with SESM died in sixty- day period.

Table 5. *Comparison of various secondary Outcome measures between various subgroups classified on the basis of pre operative biliary drainage*

	Overall (167)	No PBD (60)	PS (77)	SEMS (21)	P value (PS vs SEMS)
Median blood loss in ml (range)	500 (400-650)	500 (379-600)	500 (400-700)	570 (450-700)	0.59$
Median operating time in minutes (range)	450 (390-511)	450 (400-500)	480 (390-540)	440 (390-500)	0.33$
Median Post operative stay in days (range)	14 (10-20)	15 (10-20)	14 (10-20)	14 (11-22)	0.78$
60 day-mortality (percentage)	10 (5.9)	6 (10)	4 (5.1)	0	0.5*

30 day-readmission (percentage)	11 (6.5)	2 (3.3)	6 (7.7)	2 (9.5)	0.67*
60 day-readmission (percentage)	18 (10.7)	5 (8.3)	9 (11.7)	3 (14)	0.71*
Stay >3 weeks number (percentage)	34 (20)	10 (16)	16 (20.7)	5 (23.8)	0.76#
Complications [number (percentage)]					
Clinically significant POPF	68 (40.7)	27 (45)	34 (44)	6 (28.5)	0.19#
Clinically significant DGE	52 (31)	15 (25)	28 (36)	8 (38)	0.88#
Bleeding (all types)	20 (11.9)	11 (18)	7 (9)	1 (4.7)	1.0*
Superficial SSI	36 (21.5)	10 (16.6)	23 (30)	1 (4.7)	0.02*
Deep SSI	40 (24)	10 (16.6)	26 (33.7)	3 (1.4)	0.1*
Sepsis	57 (34)	15 (19)	32 (41)	8 (31)	0.7#
Chyle leak	15 (9)	6 (10)	6 (7.7)	3 (14)	0.3*
Bile leak	7 (4.1)	1 (1.6)	5 (6.5)	0	-

POPF- Post operative pancreatic fistula. DGE- delayed gastric emptying. SSI- surgical site infection
$- Mann Whitney U test, *- Fischer's exact test, #- Chi^2 test

Discussion

Preoperative biliary drainage in malignant lower bile duct obstruction has been focus of scientific interrogations for more than two decades [6]. Numerous retrospective studies, randomized control trials and subsequent systematic review and meta-analysis mostly failed to demonstrate that the said intervention positively influences outcome [6]. In fact, majority concluded that the PBD carries risk of more complications than upfront resection. Advances in the field of pancreatic resection has made sure a greater number of malignant bile duct obstruction are being operated safely with favourable outcome and strategies such as preoperative optimization, neoadjuvant chemotherapy [21,36] are corner stone to this. Moreover, there is tendency of centralization of pancreatic surgery to high volume center which means waiting time can go up. Consequently, preoperative biliary drainage still holds its place [28].

Van der Gaag et al while analysing the result of their RCT in 2010 observed that majority of PBD related adversities are related to the procedure itself [5]. Arguably, if procedure specific complications can be prevented PBD is unlikely to adversely affect the outcome. Physiological benefit of resolution of cholestasis before surgery has been shown in previous studies [19].

In this context metal stents started attracting attention of researchers. These were being successfully used in inoperable malignancies and benign disease to avoid surgery [19]. They are claimed to be superior to plastic stent in terms of long patency, migration and dysfunction rates making them suitable for long term use [22]. These benefits led the investigators to use them in pre-operative setting. Initially concerns were raised that placing a metal state may make surgical resection challenging and negatively affect operative and oncological outcome [19,21]. However, subsequent case series and numerous prospective studies and RCTs refuted this apprehension and claimed superiority of SEMS over PS [3,37]. Consequently, there was a paradigm shift towards preference of SEMS in preoperative biliary drainage. However, the RCTs are based on small number of cases and subsequent pulled analysis despite demonstrating superior patency are flawed by heterogeneity [6,32]. Evidence supporting SEMS not being strong practice continues to be heterogeneous in terms of indication and modality of biliary drainage.

Our retrospective review is unique in that it is first of its kind in the region and has relatively large number of cases that represented the practice in the various referring centers. We note that being cheap PS stent use is widespread and very few center like us preferred SEMS. Large number of patients were stented at a lower bilirubin level than recommended [18] without clear cut documentation of indication and most of these happens before surgical referral. However median pre-drainage bilirubin level was not significantly lower for the referred patient than ours. At the same time, we noted higher bilirubin level (severity of obstruction) did not correlate with stent related event. What is interesting is waiting time for surgery which is relatively higher than standard recommendation (two to four weeks) [24,33]. This may reflect referral bias as patients with SEMS (majority which took place at our center) were operated earlier (22 days). Risk of stent related problems (block, migration, and dysfunction) is likely to go up as the dwelling time increases. This is likely when patient waits for surgery longer than recommended. One key strategy should to expedite the surgery once PBD is done [33]. In our series the median time to stent related event in PS group was 33 days (26-32 across various aetiologies). So majority of this could have been avoided if the patients were operated earlier. In a recent randomized Cho et al showed that if the surgery could be done within two weeks from the PBS metal stent did not confer any added benefit over PS [34]. Similar inference was drawn in another prospective study by Ma et al who found that in a short-term context (three weeks) plastic stent performed equally effectively as SEMS [38].

As far as other secondary outcomes are concerned there was there no difference between the two modalities except high infection rate which again may be the result of long indwelling time of the stent increasing bacterial colonization [33]. We also noted that even in the event of stent related complication PD was not delayed significantly (37 vs 42 days).

Based on the above findings we infer that as long as successful PBD is done and surgery can take place at the earliest SESM may not confer any additional benefit over plastic stent. However, when the waiting time to surgery is expected to be longer (patient requiring chemotherapy or optimization, long wait list) SEMS may be preferred.

Conclusion

The main drawback of our study is its retrospective nature, small sample size including relatively low number of patients with SEMS and referral bias imparting heterogeneity in the plastic stent group. Nevertheless, there was a clear trend that when surgery took place sooner after drainage PS is still the cost- effective modality and does not adversely affect the outcome. Given the proven efficacy of SEMS in general though it may seem attractive to prefer it over PS, in low-income countries universal adoption of this policy needs to be supported by further randomized multicentric studies with clear criteria for PBD and standardization of waiting period.

Additional Information

Disclosures

Ethical Consideration

Tata Medical Center Institutional Review Board issued approval EC/WV/TMC/05/23. Written informed consents were obtained from all patients prior to endoscopic, percutaneous, surgical and other interventions. They had also consented for prospective data keeping and use of the same anonymously for future research.

Conflicts Of Interest

In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors declare that no financial support was received from any organization for the submitted work. **Financial relationships**: All authors declare that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors declare that there are no other relationships or activities that could appear to have influenced the submitted work.

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