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## Pre-operative stenting for benign and malignant periampullary diseases: Unnecessary if not harmful

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### Keywords

Pre-operative stenting; Obstructive jaundice; Periampullary cancer; Preoperative biliary drainage

### Introduction

While many patients are asymptomatic, one of the leading symptoms at initial presentation of patients with a periampullary tumor is pruritus from icterus/obstructive jaundice. It is established that surgery in patients with jaundice can lead to coagulopathy, infection, renal dysfunction and an increased risk of postoperative complications and worse outcomes [1,2]. Hyperbilirubinemia has been identified as a risk factor for poor outcomes in numerous studies [3–5]. It was believed that by reversing this pathophysiologic disturbance, PBD would lead to improved outcomes in patients with jaundice. Dr. AO Whipple suggested that a two-staged surgical approach, by use of bypass to reduce pre-operative hyperbilirubinemia [6], would improve hepatic function in patients with obstructive jaundice although Brunschwig at our institution reported a one-stage procedure in 1937 [7]. Currently, PBD is mostly achieved by placement of a common bile duct stent during diagnostic endoscopic retrograde cholangiopancreatography (ERCP) or alternatively by percutaneous transhepatic drainage prior to surgical intervention [8,9]. While initial studies showed that PBD may reduce postoperative mortality rates in jaundiced patients, more recent publications have challenged such results and presumed advantages of PBD [10,11]. We review the most relevant data regarding the use of PBD in patients with benign and malignant periampullary tumors and present our current practice and recommendations.

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The authors have nothing to disclose.

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## The problem: increased infectious complications with PBD

PBD prior to pancreaticoduodenectomy leads to colonization of sterile bile and consequently increases risk of infections including surgical site infection, cholangitis, and sepsis.

Numerous studies have shown that patients undergoing PBD have higher rates of positive intraoperative bile cultures and carry higher infectious-related morbidity and mortality. In an early study from our institution, Povoski reviewed 161 patients who underwent pancreaticoduodenectomy with available intraoperative bile cultures and showed positive bile cultures in 58% of patients and similar organism profiles of intraoperative bile cultures and associated blood cultures [12]. On multivariate analysis, the authors showed that PBD was associated with increased risk of postoperative infectious complications including wound infections, intra-abdominal abscess formation, and death. Together, their results suggested that PBD should be avoided due its associated complication rates.

## PBD versus early surgery: review of current data

### Randomized controlled trials

A total of 6 randomized controlled trials (RCT) have failed to show any significant clinical benefit from routine stenting and demonstrate increased postoperative complications, and poor outcome. The presumed benefits of PBD are largely theoretical.

The best designed multi-centered RCT originated from the Netherlands, examined 202 patients with perihampullary tumors and obstructive jaundice (bilirubin level 2.3 – 14.6 mg/dL) who were randomized to preoperative biliary drainage for four to six weeks versus surgery alone within one week of study enrollment [13]. The primary examined outcome was the rate of severe complications during the treatment and within 120 days of randomization. A severe complication was defined as any complication related to endoscopic biliary drainage or the surgical procedure leading to additional invasive interventions and subsequent increased length of stay, readmission for disease related morbidity, or mortality. Secondary endpoints evaluated were number of invasive procedures, costs, length of hospital stay, and quality of life. PBD was successful in 94% of the patients with a complication rate of 46%. The trial showed a lower rate of serious complications in the early surgery group compared with PBD (39% vs. 74%; RR= 0.54; 95% CI: 0.41 to 0.71;  $p<0.001$ ), with equivalent post-operative surgical complication rates, mortality, and hospital stay. Based on the increased complication and morbidity the authors concluded that routine use of PBD in patients with obstructive jaundice was not recommended.

Similarly, other RCTs have shown that PBD is associated with equivalent or higher complication rates [27–30]. Drainage-related complication rates, hospital stay, overall morbidity and mortality reported in these individual studies are summarized in Table 1.

### Retrospective studies, meta-analysis and reviews

A series of retrospective studies summarized in Table 2 have been published on this topic. Most of these show that PBD is associated with higher infectious complications [12, 14, 15], increased wound infections and intra-abdominal abscesses [12, 14, 15], pancreatic fistula rate [14], higher overall morbidity and mortality rates [12]

A meta-analysis by Sewnath [16] showed that PBD carried no benefit and thus was not recommended to be performed routinely for malignant obstructive jaundice. Similarly, a Cochrane review [17] published in 2008 demonstrated no clear evidence for routine drainage in this patient population. Most recently, Fang and colleagues [18] reanalyzed and updated the previous meta-analysis to include the newest trial by van der Gaag [13]. This study of 520 patients reviewed 6 randomized studies evaluating the safety and effectiveness of preoperative biliary drainage (n= 265) versus no drainage with early surgery (n= 255). Two out of the six randomized trials used an endoscopic approach and four used a transhepatic biliary approach with a wide range of duration of drainage in four trials (reported mean of 7–43 days and 4–6 weeks [13]). For outcomes, they assessed rate of serious morbidity and mortality, length of hospital stay, cost, and quality of life.

The data extraction was performed by 2 independent reviewers who identified higher overall serious morbidity (grade III or IV, Clavien-Dindo classification) in the PBD group compared to early surgery (RR=1.66; 95 % CI: 1.28–2.16;  $p<0.001$ ) without a significant difference in mortality (RR=1.12; 95% CI: 0.73– 1.71;  $p=0.60$ ). Additionally, the authors showed no significant difference in length of hospital stay between the two groups (mean difference of 4.48 days; 95 % CI: 1.28–11.28;  $p=0.12$ ). Quality of life and cost data was not reported in any of the trials to draw any objective conclusions about those outcomes. Based on these results, the authors concluded that combination of PBD followed by surgery increased the rate of serious complications compared with that of surgery alone without significant clinical advantages. Outcomes for serious complications and mortality and published forest plots are presented in Figures 1 and 2, respectively.

### Effects on PBD on survival

Whether PBD and the associated delay in surgery in patients with malignant pancreatic head tumors impacts survival was evaluated in a multi-center trial by Eshuis [19]. Patients with a bilirubin of 2–14 mg/dL were randomized into drainage group (PBD) for 4–6 weeks or proceed with early (<1 week) surgery (ES). The authors found that PBD and the associated delay in surgery did not impact overall survival as compared with early surgery. The median survival times were comparable 12.2 and 12.7 months in the ES and PBD group, respectively (Figure 3). There was no difference in R0 resection rates (73% in the ES group versus 62% in the PBD group). Uni- and multivariate analysis of predictive factors impacting overall survival of patients who underwent surgery is shown in Table 3.

### Plastic versus metal stents

In patients with unresectable pancreatic head tumors, metal stents are superior and preferred compared to plastic stents, whether the same is true for patients with resectable tumors when early surgery is not feasible, remains an area of controversy. This question was attempted to be answered by a meta-analysis by Crippa et al. [20], which analyzed five studies including one prospective trial [21] and 4 retrospective studies [22–25] with a total of 704 patients (Table 4). The authors evaluated rate of endoscopic re-intervention (stent failure) and overall complications as primary and secondary outcomes, respectively. They demonstrate that the rate of PBD stent failure was significantly lower in the metal stent group (3.4%) than in the

plastic group (14.8%) (OR = 0.15, 95% CI: 0.05–0.46; p=0.0009). Overall complications were lower in the metal stent group compared to the group of patients with plastic stents (OR= 0.64, 95% CI: 0.37 –1.10, p=0.11). The authors conclude that metal stents are more effective than plastic stents and should be preferred when early surgery without PBD is not feasible. This study has several limitations including the retrospective nature of majority of studies and lack of information regarding the specific stent type reported in most studies.

## Costs of PBD

Given the increased complication rate and morbidity associated with PBD as, a British group evaluated the economic implications of PBD versus direct surgery for patients with obstructive jaundice [26]. In their model, the authors estimated the mean costs and quality-adjusted life years per patient in the UK National Health Service over a 6-months and demonstrated that PBD was more costly than surgery alone (mean cost per patient \$15,616 compared to \$11,914). They reported fewer quality-adjusted life years per patient in the PBD group (mean 0.337 versus 0.343). Based on their statistical model, they calculated a cost savings of over \$3600 per patient when PBD was avoided. These results present evidence to avoid interventions which are not clinically necessary.

## Indications for pre-operative stenting for selected clinical situation

There are several clinical circumstances in which we think that PBD could be beneficial. First, one should consider PBD in patients with debilitating pruritus or in cases when further extended work up is needed or a surgical intervention cannot be scheduled for logistical reasons in a timely fashion. Another group of patients in whom PBD is recommended includes those who present with signs of systemic infections such as cholangitis and require emergent decompression. PBD is typically recommended in cases with secondary systemic organ dysfunction, most importantly compromised renal function, or anticipated major vascular reconstruction to avoid increased risks of vascular thrombosis and liver ischemia. PBD is also indicated in patients who are scheduled to receive neoadjuvant systemic therapy prior to surgical intervention. A metal stent should be used in these situations due to better stent patency and lower re-intervention and complication rates. Level of bilirubin which should stimulate a discussion as to stent or not is unknown; since 14 mg/dl has been used as the upper limit of bilirubin level in randomized controlled trials, values above that level could be used to consider stenting.

## Summary and author's recommendations

We do not recommend routine PBD in asymptomatic jaundiced patients with benign or malignant periampullary tumors prior to resection. We prefer selective PBD for patients with long-standing jaundice or cholangitis, renal impairment, severe malnutrition, neoadjuvant chemotherapy, debilitating pruritus impacting quality of life, or any special circumstance that delays a surgical procedure. We prefer the endoscopic approach for biliary drainage for periampullary tumors. Percutaneous transhepatic biliary drainage should be undertaken only in cases of failure of endoscopic approaches.

In the selected cases outlined above, we recommend admitting the patient the night before surgery for hydration to prevent postoperative renal insufficiency. Despite the lack of benefit proven by several level 1 data, most patients are evaluated and stented prior to surgical evaluation. We stress the need for comprehensive surgical evaluation prior to a decision as to invasive biliary drainage.

## Acknowledgments

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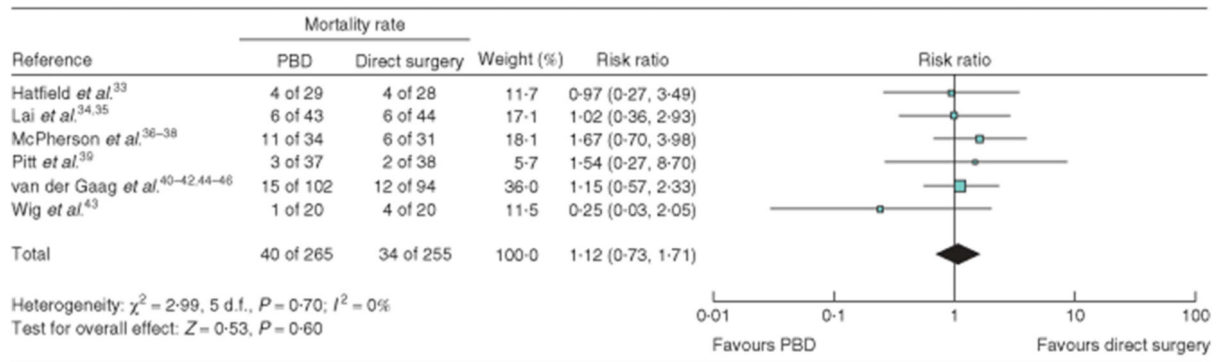
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**Key Points**

- Preoperative biliary drainage (PBD) is often performed in patients with jaundice with the presumption that it will decrease the risk of post-operative complications.
- PBD carries its own risk of complications and therefore has been controversial.
- Multiple randomized controlled trials and meta-analyses have shown that PBD has significantly increased overall complications compared to surgery alone.
- The routine application of PBD should be avoided except in a subset of clinical situations.

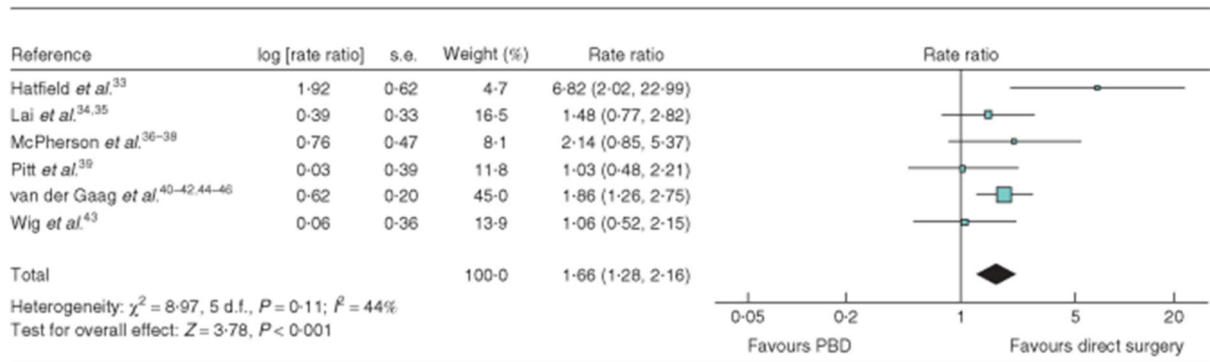
### Synopsis

Preoperative biliary drainage (PBD) is often performed in patients with jaundice with the presumption that it will decrease the risk of post-operative complications. PBD carries its own risk of complications and therefore has been controversial. Multiple randomized controlled trials and meta-analyses have shown that PBD has significantly increased overall complications compared to surgery alone. As such, the routine application of PBD should be avoided except in a subset of clinical situations as discussed in detail in this article.

**Figure 1.**

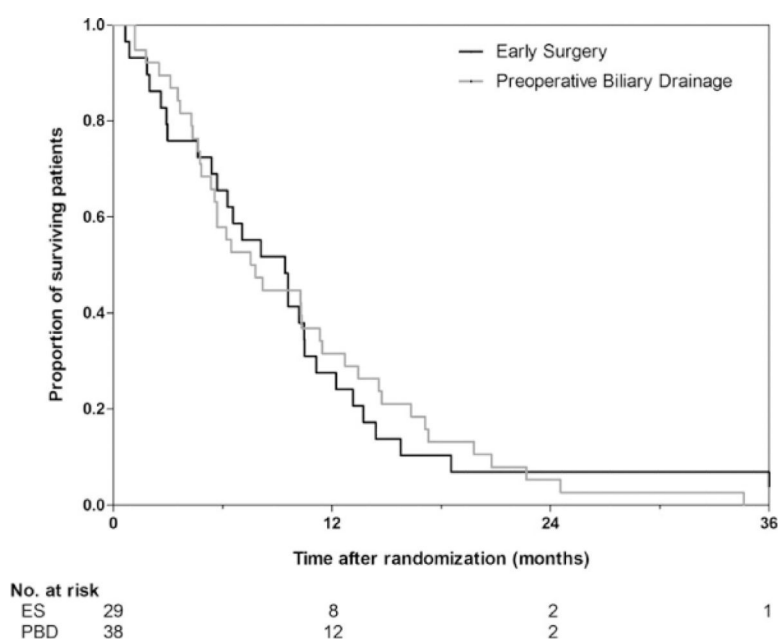
Mortality rates and forest plot of randomized trials reported on preoperative biliary drainage (PBD) before surgery compared to direct surgery. A Mantel-Haenszel fixed-effect model was used for meta-analysis. Risk ratios are shown with 95% confidence intervals.

From Fang Y, Gurusamy KS, Wang Q, et al. Meta-analysis of randomized clinical trials on safety and efficacy of biliary drainage before surgery for obstructive jaundice. *Br J Surg* 2013; 100(12):1589–1596, with permission.

**Figure 2.**

Adverse events in trials that used preoperative biliary drainage (PBD) before surgery and those that did not (direct surgery). Data are shown in a logarithmic scale. An inverse-variance fixed-effect model was used for meta-analysis. Rate ratios are shown with 95% confidence intervals.

From Fang Y, Gurusamy KS, Wang Q, et al. Meta- analysis of randomized clinical trials on safety and efficacy of biliary drainage before surgery for obstructive jaundice. *Br J Surg* 2013; 100(12):1589–1596, with permission.



**Figure 3.** Overall survival of patients with malignant pancreatic head tumors who were randomized to early surgery (ES) or preoperative biliary drainage (PBD) and underwent subsequent resection.

From Eshuis WJ, van der Gaag NA, Rauws EA, et al. Therapeutic delay and survival after surgery for cancer of the pancreatic head with or without preoperative biliary drainage. *Ann Surg.*2010; 252(5):840–849, with permission.

**Table 1.** Randomized controlled trials of preoperative biliary drainage (PBD) versus direct surgery (DS) for obstructive jaundice

| Study                      | Year | Total Number of patients | Treatment Group | Number of patients | Drainage route | Drainage related complication rate (%) | Hospital stay (days) | Morbidity (%) | Mortality N (%) |
|----------------------------|------|--------------------------|-----------------|--------------------|----------------|--|----------------------|---------------|-----------------|
| Hatfield <sup>27</sup>     | 1982 | 57                       | PBD             | 28                 | PTBD           | >50                                    | N/A                  | 14            | 4 (14)          |
|                            |      |                          | DS              | 29                 |                |  |                      | 14            | 4 (14)          |
| Lai <sup>28</sup>          | 1994 | 87                       | PBD             | 43                 | Endoscopic     | 28                                     | N/A                  | 37            | 6 (14)          |
|                            |      |                          | DS              | 44                 |                |  |                      | 41            | 6 (14)          |
| McPherson <sup>29</sup>    | 1984 | 65                       | PBD             | 34                 | PTBD           | >50                                    | 40                   | 39            | 11 (31)         |
|                            |      |                          | DS              | 31                 |                |  | 23                   | 41            | 6 (19)          |
| Pitt <sup>30</sup>         | 1985 | 75                       | PBD             | 37                 | PTBD           | 27                                     | 31                   | 57            | 3 (8)           |
|                            |      |                          | DS              | 38                 |                |  | 23                   | 53            | 2 (5)           |
| Van der Gaag <sup>13</sup> | 2010 | 202                      | PBD             | 102                | Endoscopic     | 46                                     | 15                   | 47*           | 15(15)          |
|                            |      |                          | DS              | 96                 |                |  | 13                   | 37            | 12(13)          |

PTBD- Percutaneous transhepatic biliary drainage

\* Indicates statistically significant difference with  $p < 0.05$

Retrospective series of pre-operative biliary stent versus no stent for obstructive jaundice

Table 2.

| Reference                | Year | N   | Group     | Infectious complications (%) | Wound infections (%) | Intra-abdominal abscess(%) | Pancreatic leak/fistula (%) | Morbidity (%)   | Mortality (%)  |
|--------------------------|------|-----|-----------|------------------------------|----------------------|----------------------------|-----------------------------|-----------------|----------------|
| Povosky <sup>12</sup>    | 1999 | 126 | Stented   | 41 <sup>*</sup>              | N/A                  | 19 <sup>*</sup>            | N/A                         | 55 <sup>*</sup> | 8 <sup>*</sup> |
|                          |      | 114 | Unstented | 25                           | N/A                  | 8                          | N/A                         | 39              | 3              |
| Sohn <sup>31</sup>       | 2000 | 408 | Stented   | 32                           | 10                   | 4                          | 10                          | 35              | 2              |
|                          |      | 159 | Unstented | 22                           | 4                    | 6                          | 4                           | 30              | 3              |
| Pisters <sup>32</sup>    | 2001 | 172 | Stented   | 37                           | 13 <sup>*</sup>      | 39                         | 0                           | 88              | 1              |
|                          |      | 93  | Unstented | 31                           | 4                    | 37                         | 0                           | 86              | 1              |
| Martignoni <sup>33</sup> | 2001 | 99  | Stented   | 25                           | 5                    | 0                          | 1                           | 50              | 2              |
|                          |      | 158 | Unstented | 22                           | 6                    | 3                          | 3                           | 45              | 3              |
| Srivastava <sup>14</sup> | 2001 | 54  | Stented   | 52 <sup>*</sup>              | 43 <sup>*</sup>      | 28 <sup>*</sup>            | 20 <sup>*</sup>             | 48              | 15             |
|                          |      | 67  | Unstented | 29                           | 24                   | 15                         | 5                           | 46              | 12             |
| Sewnath <sup>16</sup>    | 2002 | 232 | Stented   | 37                           | 7                    | 16                         | 14                          | 50              | 1              |
|                          |      | 58  | Unstented | 31                           | 9                    | 16                         | 7                           | 55              | 0              |
| Mezhir <sup>15</sup>     | 2009 | 94  | Stented   | 32 <sup>*</sup>              | 20 <sup>*</sup>      | 12 <sup>*</sup>            | 4                           | 51              | 0              |
|                          |      | 94  | Unstented | 13                           | 7                    | 3                          | 6                           | 41              | 5              |
| Coates <sup>34</sup>     | 2009 | 56  | Stented   | 18                           | 5                    | 7                          | 7                           | 37              | 4              |
|                          |      | 34  | Unstented | 21                           | 9                    | 12                         | 12                          | 47              | 15             |

\* Indicates statistically significant difference between “stented” and “unstented” group with  $p < 0.05$ .

N/A indicates data not available.

Uni – and multivariate analysis of predictive factors for overall survival in 180 patients who underwent surgery for a malignant pancreatic head mass.

**Table 3.**

|  | Univariable, HR (95% CI) | Multivariable, HR (95%) |
|--|--------------------------|-------------------------|
| Time from randomization to surgery 1-week increment            | 0.98 (0.92–1.05)         | 0.91 (0.84–0.99) *      |
| Age, 1-year increment **                                       | 1.00 (0.98–1.02)         | 1.00 (0.98–1.01)        |
| Female sex   | 1.06 (0.76–1.48)         | 1.26 (0.87–1.80)        |
| Bilirubin at randomization (quartiles), one quartile increment | 1.17 (1.01–1.35) *       | 1.22 (1.04–1.43) *      |
| Underwent preoperative biliary drainage                        | 0.90 (0.65–1.24)         | NA                      |
| Resection of tumor   | 0.32 (0.23–0.46) ***     | 0.28 (0.20–0.41) ***    |
| Blood transfusion intraoperatively                             | 1.10 (0.71–1.71)         | 1.25 (0.79–1.98)        |
| Complications related to PBD and/or surgery                    | 1.09 (0.79–1.51)         | 1.45 (1.01–2.09) *      |

\* Significant at P<0.05 level

\*\* At the time of surgery

\*\*\* Significant at P<0.01 level

CI, confidence interval; HR, hazard ratio; NA, not applicable; PBD, preoperative biliary drainage

From Eshuis WJ, van der Gaag NA, Rauws EA, et al. Therapeutic delay and survival after surgery for cancer of the pancreatic head with or without preoperative biliary drainage. *Ann Surg*. 2010; 252(5): 840–849, with permission.

Summary of studies comparing plastic versus metal stents and reported rates of stent failure, overall complications, and postoperative mortality rates

**Table 4.**

| Reference               | Year | Study Design            | Total number of patients | Type of stent (N)           | Rate of stent failure (%) | Overall complications rate related to drainage before surgery (%) | Overall pancreatic anastomotic leak (%) | Overall post-operative mortality (%) |
|-------------------------|------|-------------------------|--------------------------|-----------------------------|---------------------------|---|---|--------------------------------------|
| Tol <sup>21</sup>       | 2015 | Prospective multicenter | 151                      | Plastic (102)<br>Metal (49) | 30<br>4                   | 46<br>24  | 8<br>2                                  | 15<br>6                              |
| Hapanaaki <sup>22</sup> | 2014 | Retrospective           | 191                      | Plastic (163)<br>Metal (28) | 7<br>3                    | 3<br>4  | 15<br>7                                 | 0<br>0                               |
| Cavell <sup>23</sup>    | 2013 | Retrospective           | 220                      | Plastic (149)<br>Metal (71) | N/A<br>N/A                | N/A<br>N/A  | 13<br>7                                 | 0<br>0                               |
| Adams <sup>24</sup>     | 2012 | Retrospective           | 113                      | Plastic (70)<br>Metal (43)  | N/A<br>N/A                | 21<br>3   | N/A<br>N/A                              | N/A<br>N/A                           |
| Decker <sup>25</sup>    | 2011 | Retrospective           | 29                       | Plastic (18)<br>Metal (11)  | 39<br>0                   | N/A<br>N/A  | 0<br>0                                  | N/A<br>N/A                           |

N/A indicates data not available.