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Changes in preoperative endoscopic and percutaneous bile drainage in patients with periampullary cancer undergoing pancreaticoduodenectomy in Ontario: effect on clinical practice of a randomized trial

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ABSTRACT

Background In 2010, a multicentre randomized controlled trial reported increased postoperative complications in pancreaticoduodenectomy (PDE) patients undergoing preoperative biliary decompression (PBD). We evaluated the effect of that publication on rates of PBD at the population level.

Methods This retrospective observational cohort study identified patients undergoing PDE for malignancy, 2005–2013, linking them with administrative health care databases covering medical services for a population of 13.5 million. Patients undergoing PBD within 6 weeks before their surgery were identified using physician billing codes and were divided into those undergoing PDE before and after article publication, with a 6-month washout period. Chi-square tests were used to compare rates of PBD.

Results Of 1997 PDE patients identified, 963 underwent surgery before article publication, and 911, after (123 during the washout period). The rate of PBD was 47.5% before publication, and 41.6% after ($p = 0.01$). The lowest PBD rates occurred immediately after publication, in 2010 and 2011. Similar results were observed when the cohort was restricted to patients seen preoperatively by a gastroenterologist ($n = 1412$).

Conclusions Rates of PBD have declined a small, but significant, amount after randomized trial publication. Persistence of PBD might relate to suboptimal knowledge translation, the role of PBD in diagnosis of periampullary malignancy, and treatment of complications (cholangitis, severe hyperbilirubinemia) or anticipation of delay from diagnosis to surgery. The nadir in PBD rates after article publication and the subsequent rise suggest an element of transience in the effect of article publication on clinical practice. Further investigation into the reasons for persistent PBD is needed.

Key Words Pancreatic neoplasia, resection, periampullary tumours, outcomes

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INTRODUCTION

Malignant tumours of the periampullary region often obstruct biliary drainage as they enlarge, resulting in hyperbilirubinemia and jaundice at presentation in 47%–90% of patients[1–3]. Substantial controversy has arisen about the benefits of preoperative interventions to decompress the blocked biliary ducts and relieve jaundice before pancreaticoduodenectomy (PDE) in patients with tumours amenable to surgical resection[4]. Obstructive jaundice has been hypothesized to impair hemostasis, immune function, and wound healing; preoperative biliary decompression (PBD) before PDE has therefore been routinely performed for many years[5–9]. However, mounting

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evidence suggests that, contrary to its theoretical benefits, routine PBD of jaundiced patients is associated with increased morbidity—specifically, increased infectious complications[1,2,10–13].

In January 2010, a multicentre prospective randomized controlled trial (RCT) published by van der Gaag *et al.*[14] in the *New England Journal of Medicine* reported that morbidity was increased in patients undergoing PBD compared with patients who proceeded directly to surgery. The DROP trial randomized 202 jaundiced patients with resectable cancers of the pancreatic head and no evidence of cholangitis either directly to surgery (PDE within 1 week of diagnosis) or to PBD (biliary drainage for 4–6 weeks, followed by PDE)[14,15]. In the PBD group, patients experienced nearly double the rate of serious complications [74% vs. 39%; relative risk: 0.54; 95% confidence interval (CI): 0.41 to 0.71] seen in the direct-to-surgery group. Infectious complications (wound infection, pneumonia, cholangitis) in particular were more common in the PBD patients. The authors concluded that routine PBD led to increased complications and did not confer any benefit with respect to outcomes[14]. The study provided level I evidence favouring direct surgery over PBD[16]. To ascertain the impact of level I evidence on actual clinical practice, we assessed the effect of the DROP study on rates of PBD before PDE by comparing PBD rates at the population level before and after publication of the RCT.

METHODS

This population-based observational cohort study used administrative health care data from databases held at the Institute for Clinical Evaluative Sciences (ICES) that were linked using unique patient identifiers. The linked databases included the Discharge Abstract Database maintained by the Canadian Institute for Health Information, the OHIP (Ontario Health Insurance Plan) database, the Registered Persons Database, and the Ontario Cancer Registry. The Discharge Abstract Database contains dates and details of all hospital admissions of more than 24 hours' duration in the province[17]. The OHIP database contains dates of all medically necessary consultations and interventions billed by a physician in the province (including those related to periampullary malignancy). The Registered Persons Database contains patient sociodemographic information, and the Ontario Cancer Registry contains histopathologic details for all oncologic resection specimens in Ontario.

Patients undergoing PDE in the province of Ontario (population 13.5 million[18]) between 1 April 2005 and 30 September 2013 were identified from discharge records in the Discharge Abstract Database (Canadian Classification of Health Interventions codes 1.OK.87 and 1.OK.91), as previously described[19]. The cohort was further restricted to patients diagnosed with a periampullary malignancy within 6 months of undergoing PDE. Periampullary malignancy was defined using the *International Classification of Diseases for Oncology* (3rd edition) topography and histology or behavior codes contained in the Ontario Cancer Registry database. Patients treated with neoadjuvant chemotherapy (defined using OHIP billing codes for administration of chemotherapy in the 365 days before PDE) were excluded from the analysis.

The primary outcome of interest, PBD, was identified using OHIP billing codes for endoscopic retrograde cholangiopancreatography (Z558, Z561, and Z760), percutaneous transhepatic cholangiography (J013 and S233), and bile duct intubation for obstruction (Z542). In accordance with the definition used by van der Gaag *et al.* in their study, PBD was defined as occurring within 42 days (6 weeks) before the date of the PDE surgery. Preoperative biliary decompression was defined as a binary categorical variable, in that each patient either underwent PBD or did not; patients who underwent multiple PBD procedures were not distinguished.

To ascertain the effect of the publication of the van der Gaag *et al.* multicentre RCT recommending against PBD before PDE, the patient cohort was split into a pre-publication group and a post-publication group, with a 6-month washout period surrounding publication of the RCT results in January 2010. The pre-publication group underwent PDE between 1 April 2005 and 30 September 2009, and the post-publication group underwent PDE between 1 April 2010 and 30 September 2013. Chi-square tests were used to compare unadjusted rates of PBD between the pre- and post-publication groups, and between the pre-publication, post-publication, and washout groups. Rates of PBD were also stratified by year of PDE surgery and compared by chi-square test. A sensitivity analysis was performed restricting the cohort to patients who were seen in preoperative consultation by a gastroenterologist (identified using OHIP codes A415, C415, A135, and C135) within 100 days before surgery.

Logistic regression with backward elimination of covariates at $p > 0.2$ was used to identify independent predictors of PBD, with adjustment for these covariates: time period, age, sex, comorbidity, socioeconomic status[20,21]. Age, sex, and socioeconomic status were defined using data from the Registered Persons Database. Geographic location of primary residence was used to define socioeconomic status, representing both rural or urban location and median neighbourhood income relative to other incomes in the geographic region (categorized from lowest to highest income quintile) based on census data, as previously described[22]. To evaluate rurality while avoiding collinearity with median income, a hybrid variable termed "socioeconomic status" was created, wherein all rural patients were grouped into a single category[23]. Comorbidity burden was defined using the Johns Hopkins (Baltimore, MD, U.S.A.) Adjusted Clinical Groups system, based on the International Classification of Diseases (revision 10) diagnostic codes for each patient in the preceding 24 months; codes are then summed to generate a score from 0 to 32 (increasing values representing increasing comorbidity burden). To optimize model stability, a two-level categorical version of the variable with a cut-point of 10 was used as has previously been described[20,21]. Results are presented as adjusted odds ratios (ORs) for undergoing PBD, with 95% confidence intervals (CIs). Two-sided hypothesis testing was performed, and an alpha of 0.05 was used to establish statistical significance.

All analyses were performed at ICES using the SAS software application (version 9.2: SAS Institute, Cary, NC, U.S.A.). Appropriate research ethics board approval for this project was obtained at Sunnybrook Health Sciences Centre and at ICES.

RESULTS

From 2005 to 2013, 2660 patients with linkable unique identifiers underwent PDE in Ontario (26 patients were excluded because of missing identifiers). Of those 2660 patients, 2053 had a diagnosis of periampullary malignancy. The 56 patients who received neoadjuvant therapy were excluded. The remaining 1997 patients formed the cohort subject to analysis. Based on date of surgery, that cohort was then subdivided into a pre-publication group (n = 963, PDE occurring before 1 October 2009), a post-publication group (n = 911, PDE occurring after 31 March 2010), and a washout group (n = 123, PDE occurring between 1 October 2009 and 31 March 2010). Table I presents the baseline clinical and sociodemographic characteristics of those groups (8 patients excluded because of missing socioeconomic status).

Of the 1997 periampullary cancer patients who underwent PDE, 886 underwent PBD within the 6 weeks before surgery (44.4%). A significant decline in the rate of PBD use was observed from the pre-publication group (47.5%) to the post-publication group (41.6%, p = 0.011, Figure 1). A similar decline in the annual rate of PBD was also observed, to 40.2% in 2013 from 52.5% in 2005 (p = 0.05, Figure 2). Interestingly, the lowest annual rates of PBD were observed in 2010 (39.3%) and 2011 (38.7%), immediately after publication of the RCT. Those findings persisted when the cohort was restricted to patients seen preoperatively by a gastroenterologist (n = 1412), with 54.2% of patients undergoing PBD in 2005, declining to 43.8% of patients in 2013 (p = 0.16, Figure 3).

After multivariate logistic regression adjusting for covariates, the likelihood of undergoing PBD was found to be significantly lower for patients in the post-publication

TABLE I Clinical characteristics of 1997 patients undergoing pancreaticoduodenectomy for malignant indication in the periods before and after the publication of van der Gaag *et al.,* 2010[14], with a 6-month washout period

Variable	Relation of patient group to publication		
	Before	Washout	After
Patients *(n)*	963	123	911
Age group			
≤60 Years	323	33	278
61–70 Years	313	47	319
71–80 Years	283	34	259
≥81 Years	44	9	55
Sex			
Women	421	51	380
Men	542	72	531
Comorbidity group (by score on the ACG[a])			
0–9	372	51	357
10–32	591	72	554
Socioeconomic status[b]			
Urban 5	193	26	187
Urban 4	165	24	160
Urban 3	175	20	137
Urban 2	161	33	163
Urban 1	136	12	142
Rural	130	8	117

[a] Johns Hopkins Adjusted Clinical Groups system (used with permission).
[b] This data point was missing for 8 patients.

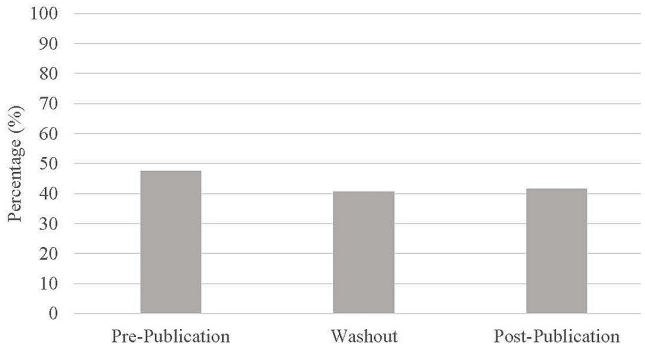

FIGURE 1 Rates of preoperative biliary drainage in 1997 patients undergoing pancreaticoduodenectomy for cancer in the pre-publication, washout, and post-publication periods (p = 0.03).

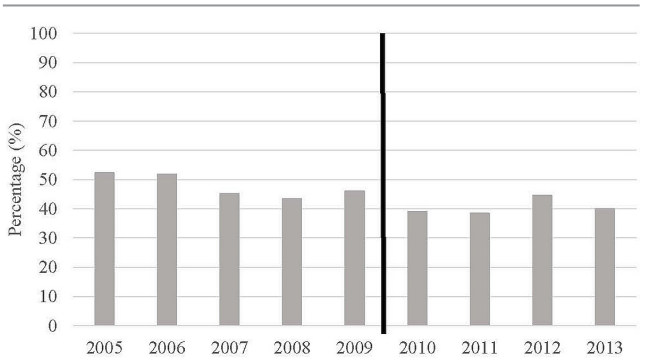

FIGURE 2 Rates of preoperative biliary drainage in 1997 patients undergoing pancreaticoduodenectomy for cancer by year of surgery (p = 0.05). The vertical line denotes article publication.

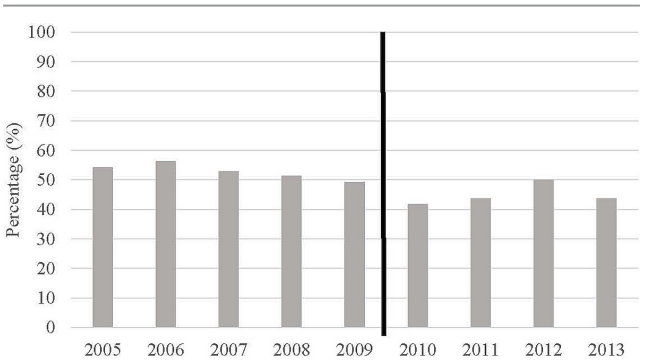

FIGURE 3 Rates of preoperative biliary drainage in 1412 patients undergoing pancreaticoduodenectomy for cancer who were seen preoperatively by a gastroenterologist (p = 0.16). The vertical line denotes article publication.

period than for patients in the pre-publication period (OR: 0.794; 95% CI: 0.661 to 0.955; Table II). Additionally, compared with patients living in the highest-income urban neighbourhoods, those living in the lowest-income urban neighbourhoods had a significantly lower likelihood of undergoing PBD (OR: 0.677; 95% CI: 0.497 to 0.922). Living in a rural area was not associated with undergoing PBD (OR: 0.843; 95% CI: 0.614 to 1.157). An association of PBD with age ($p = 0.850$), sex ($p = 0.652$), or comorbidity burden ($p = 0.557$) was not observed.

DISCUSSION

In the present study, we compared rates of PBD before PDE for periampullary cancer before and after publication of a multicentre RCT demonstrating inferior outcomes with PBD, identifying a decline to 41.6% after article publication from 47.5% before publication. Previously published single- and multi-institutional studies have reported PBD rates ranging from 40% to 72%[9,12,24–27]. The decline in PBD rates after publication of the van der Gaag *et al.* RCT is small, but convincingly present. Although the reduction in PBD might be related to secular trends and a general tendency away from routine PBD, the putative influence of van der Gaag's article is underscored by the observation that the lowest rates of PBD occurred in 2010 and 2011, immediately after the article's publication. Furthermore, that nadir in PBD rates and the subsequent rise suggests an element of transience in the effect of article publication, wherein the effect on practice patterns is most pronounced immediately after publication, and then diminishes slightly over time. Other possible explanations for that observation include the subsequent publication of large single-institution series reporting no increase in overall morbidity associated with PBD[28]. Despite the inferior methodologic rigour of results emerging from retrospective series compared with those derived from a RCT, the results of those series might undermine the conclusions of van der Gaag *et al.* and contribute to clinical equipoise with respect to PBD[14,28].

Although the reduction in the PBD rate after publication of the RCT was statistically significant, the magnitude of decrease was relatively small, and a substantial proportion of patients with periampullary malignancy were still undergoing PBD at the end of the study period. That situation might partly be attributable to a lack of effective knowledge translation and suboptimal uptake of evidence in clinical practice, but several other factors likely contributed to the persistence of PBD before PDE[29]. Patients presenting with painless jaundice might have undergone endoscopic retrograde cholangiopancreatography with stent insertion as an initial step in their work-up and, hence, were diagnosed with periampullary malignancy only once a PBD had been performed. Others might have required urgent PBD for cholangitis or severe hyperbilirubinemia.

The logistics of completing a preoperative work-up and scheduling an urgent PDE outside the auspices of a clinical trial can require a considerable amount of time, and anticipation of a delay from diagnosis to surgery could possibly be contributing to the persistence of PBD[30]. Initial referral of most patients to a gastroenterologist instead of a surgeon might further contribute to uncertainty about the time to PDE and bias practitioners toward performing PBD. Furthermore, physicians might possibly doubt the applicability of the RCT's findings to their clinical practice, given the challenges of performing a PDE within 1 week of diagnosis. One potential mechanism for addressing those barriers to evidence uptake is the implementation of health care policy designed to encourage early involvement of surgeons and to facilitate timely PDE. Notably, the longer time to surgery associated with PBD and resolution of jaundice might not be detrimental to patient outcomes. In fact, some data suggest that delay to surgery might confer a protective effect against mortality in the postoperative period, although the mechanism underlying that observation is unclear[31].

Limitations of the present study include its retrospective observational design, with the resultant potential for selection bias and confounding by indication. Based on the administrative databases interrogated, it is not possible to know which patients in the cohort were jaundiced or cholangitic, or what their intended management plan was. However, the incidence of jaundice—and clear indications for PBD (cholangitis, severe hyperbilirubinemia)—would be expected to be stable over the study time period, and there is no reason to expect a change with publication of the van der Gaag *et al.* RCT. In addition, the definition of PBD was based on biliary instrumentation; patients who underwent unsuccessful PBD, or multiple attempts at PBD, were therefore not distinguished. However, PBD is, with multiple attempts, successful in more than 94% of patients, suggesting that almost all patients identified as having undergone PBD in the present study actually achieved biliary drainage[14,32]. Finally, the finding of a correlation between RCT publication and the observed slight decrease in PBD rates could potentially be spurious, the result of a type 1 error or confounding variables both known and unknown; accordingly, conclusions should be drawn with caution.

TABLE II Independent predictors of preoperative biliary drainage in 1989 patients by logistic regression[a]

Variable	Adjusted odds ratio	95% CL	
		Lower	Upper
Time period[b]			
Before	Reference		
Washout	0.745	0.508	1.093
After	**0.794**	**0.661**	**0.955**
Socioeconomic status			
Urban 5	Reference		
Urban 4	0.994	0.746	1.325
Urban 3	1.015	0.759	1.359
Urban 2	0.949	0.712	1.263
Urban 1	**0.677**	**0.497**	**0.922**
Rural	0.843	0.614	1.157

[a] Using backward elimination of covariates at $p>0.2$ (eliminated: age, sex, comorbidity). Adjusted odds ratios, with 95% confidence intervals are presented. Boldface type indicates significance.

[b] In relation to the publication by van der Gaag *et al.,* 2010[14].

OR = odds ratio; CL = confidence limits.

CONCLUSIONS

In the present study, we used a large series of patients undergoing PDE for periampullary malignancy across a heterogeneous population of patients and providers to report on the uptake in clinical practice of high-level RCT evidence. The results demonstrate a significant decrease in the rate of PBD use after publication of a pertinent RCT, although the magnitude of the decrease was relatively small. Numerous patients still undergo PBD before PDE. Putative contributing factors include established referral patterns and the time delay until surgery. Further investigation is needed into the reasons for performing PBD; into practice variation at the regional, institutional, and provider levels; and into barriers and facilitators to incorporation of best evidence into routine clinical practice. The potential for health care policy to improve the uptake of new evidence in this area should also be explored.

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CONFLICT OF INTEREST DISCLOSURES

We have read and understood *Current Oncology*'s policy on conflicts of interest, and we declare that we have none.

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