

ORIGINAL ARTICLE

Epidural analgesia for hepatopancreatobiliary operations and postoperative urinary tract infections: an unrecognized association of “best-practices” and adverse outcomes

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Abstract

Background: Thoracic epidural analgesia (TEA) is considered “best-practices” for pain-control following HPB operations. It is unknown if TEA increases the risk of UTI. We sought to examine the association of TEA and UTI following HPB operations.

Methods: A retrospective cohort study of patients undergoing elective HPB operations was performed (ACS-NSQIP [2014–2016]). Patients were categorized by TEA utilization. The primary outcome was UTI. Multivariable logistic regression models were created to examine the association of TEA with UTI; including sensitivity and interaction analyses for age and gender.

Results: Among 28,571 patients included, 5764 (20.2%) had TEA. UTI occurred more frequently with TEA (3.5% vs. 2.2%, $p < 0.01$). After multivariable analysis, TEA was associated with increased risk of UTI (1.59 [1.34–1.89]); when stratified by age and gender, the association persisted with an incremental increased risk observed in males over 70 years (1.91 [1.41–2.59]). UTI was associated with increased risk of sepsis (16.8% vs. 5.6%, $P < 0.001$), LOS (9 versus 6 days, $P < 0.001$) and readmission rates (21.4% vs. 12.3%, $P < 0.001$).

Conclusion: Despite TEA recommended as a best-practice standard for HPB operations, the increased risk of UTI calls for evaluation of current practices and consideration of alternative strategies for high-risk vulnerable populations – elderly males.

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Introduction

Enhanced Recovery after Surgery (ERAS) protocols for hepatobiliary and pancreas (HPB) operations^{1,2} have proven to be beneficial in reducing length of stay, decreasing cost, and improving clinical and patient reported outcomes, and are considered “best-practices” for the perioperative care of this and

other surgical populations.^{3–5} ERAS-based perioperative care protocols are, by definition, bundle-care pathways with multiple interventions targeting different components of the physiologic response to surgery, and each typically considered the standard for the corresponding domain. However, it is unclear if an individual component within the ERAS framework is more significant than others in contributing to these improved outcomes; and whether an intervention may have a detrimental effect on a specific outcome or population, despite a perception of overall benefit when implementing the ERAS pathway.

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Pain control is a critical domain of perioperative care targeted in ERAS protocols and has important benefits with respect to stress response, return of bowel function/early diet tolerance, and length of hospital stay.^{3–5} Further, in the context of the national opioid epidemic,⁶ a judicious analgesic strategy must also focus on minimizing (avoiding) overall use of and potential dependence to narcotic medications, with implementation of ERAS protocols showing a decrease need for post-discharge narcotic medications.⁷ The use of thoracic epidural analgesia (TEA) is considered among best-practices options for perioperative pain control in HPB operations, and is recommended over intravenous (IV) opioid-based patient-controlled analgesia (PCA) in hepatobiliary and pancreatic ERAS protocols.^{1,2,8} Advantages of epidural analgesia include superior pain control, lower complication rate, increased patient satisfaction, and lower costs and total postoperative opioid consumption.^{8–10} Nonetheless, other studies have reported worse outcomes in patients treated with TEA.^{11,12} Specifically, the use of TEA is associated with urinary retention due to its action on lumbosacral fibers which can block afferent and efferent signals to the bladder.¹³ Despite recommendations for removal of indwelling bladder catheters within 48 h of surgery as a standard infection prevention practice,¹⁴ patients with TEA typically have a urinary catheter for more prolonged periods of time – often while the epidural is in place. It is currently unknown if TEA is associated with an increased risk of postoperative urinary tract infections (UTI) for this population of patients, and if such association may be dependent on gender and/or age, given a higher risk of urinary retention experienced by older males with enlarged prostate.

Based on the above considerations, we sought to examine the utilization of epidural analgesia for HPB operations and its association with postoperative UTI. We hypothesized there is an increased risk of UTI in patients having HPB operations and treated with TEA as compared to those without, and that risk would be significantly higher in elderly-male patients. We find value in examining the effect of TEAs on overall outcomes for the elderly, as UTIs are among the most common complications contributing significantly to other adverse events in this vulnerable population (e/g., readmissions, ICU stay and mortality),¹⁵ as well as a driver for healthcare costs. Further, TEA utilization represents an actionable factor related to daily practices across different settings. To mitigate the confounding effect of differences in perioperative practices across institutions, we used a national clinical quality and outcomes registry to have a more generalized representation of the association, in a real-world setting.

Methods

We performed a retrospective cohort study using the American College of Surgeons – National Surgical Quality Improvement Program (ACS-NSQIP) database from 2014 to 2016, to examine the association between the use of perioperative epidural

analgesia and incidence of postoperative urinary tract infections (UTI), for patients having hepato-pancreato-biliary (HPB) operations. ACS-NSQIP is a national prospectively collected registry of surgical patients with data captured by trained registrars across participating hospitals ($N > 1500$).¹⁶ It is a validated registry that accurately captures postoperative outcomes and adverse events, and is specially designed to distinguish these postoperative events from other perioperative data including baseline comorbid conditions and other preoperative risk factors. Patients having major elective hepatobiliary (47120, 47122, 47125, 47130, 47785) and pancreatic operations (48120, 48140, 48145, 48146, 48150, 48152, 48153, 48154, 48548) requiring inpatient care were identified using CPT codes and included. Those having emergent operations, preoperative infections (i.e., sepsis or UTI diagnosed on POD 0), acute or chronic preoperative renal insufficiency on dialysis, and patients who were ventilator dependent preoperatively were all excluded. Similarly, patients discharged on postoperative day 0, those with postoperative ventilator use >48 h, and those who died within 48 h of the operation were also excluded.

The primary outcome of interest was the occurrence of postoperative UTI, as defined by ACS-NSQIP ([Supplemental Digital Content 1](#)). The intervention/independent variable of interest was use of epidural analgesia during the perioperative period; this was ascertained using the ‘Anesth_Other’ variable, which defines the use of secondary anesthesia administered in addition to the primary anesthesia technique (general anesthesia) Secondary outcomes included the association between UTI and other postoperative outcomes including postoperative sepsis, reoperation and mortality, as well as outcomes of healthcare utilization including unplanned readmission and hospital length of stay (LOS). Demographic data (age, gender, race, ethnicity), as well as clinical (ASA score), comorbidity, and functional status information were all recorded and included as covariates. A complete-case analysis was performed for a final study sample of 28,571 patients.

Descriptive statistics were performed for the cohort and also by group based on the intervention – epidural vs. no epidural. Continuous variables are presented as medians and compared using the Mann–Whitney U test. Categorical variables are presented as proportions and compared using the Chi-squared test. Unadjusted (univariable) logistic regression analysis was performed to examine the association between use of epidural catheter, and each of the covariates, with the primary outcome of interest – UTI. Similarly, the association between UTI and secondary outcomes was also examined using univariable and multivariable models. Adjusted (multivariable) logistic regression models were created to examine the association of epidural analgesia with UTI, accounting for prespecified, clinically relevant covariates. In the multivariable model, we included covariates hypothesized to be associated with the outcome and those with a $p < 0.25$ in univariable analysis. The strength of the association is presented as odds ratios (OR) with 95% confidence

intervals (95% CI). Performance of the models – discrimination and calibration – was evaluated using the area under the receiver operating characteristic (ROC) curve and the Hosmer–Lemeshow statistic, respectively. To account for differences in the association between genders, we performed sensitivity analyses, and additional multivariable regression models were developed for both females and males. To further examine this difference and the contribution of age (interaction), we did additional bivariable analysis, based on epidural utilization, by gender and age. All associations were considered statistically significant with a $p < 0.05$. Statistical analyses were performed using Stata Statistical Software, release 15.1, from StataCorp LLC, College Station, TX.

Results

In all, 28,571 patients met inclusion criteria and represented the study sample. Of these, 5764 (20.2%) had epidural analgesia during the perioperative period. The demographic and baseline clinical characteristics of the study sample are depicted in Table 1. Notably, close to one-third of patients were over the age of 70, and there was no difference in the age or gender distribution based on use of epidural analgesia. Patients in the epidural

group had functional dependence less commonly than those in the non-epidural group, although the overall clinical difference was small (0.45% vs. 0.7%; $p < 0.01$). There was higher epidural analgesia utilization in those having pancreatic operations compared to those having hepatobiliary procedures, although this difference was not statistically significant (22.1% vs. 17.4%; $p = 0.07$).

Primary outcome – univariable and multivariable analysis

A total of 696 patients developed UTI following surgery (2.44%). UTI occurred more frequently in patients treated with TEA as compared to those without (3.5% vs. 2.2%; $P < 0.01$). On univariable analysis, use of epidural analgesia was associated with higher odds of developing a UTI (OR 1.61 [95% CI 1.36–1.90]; $P < 0.01$). Results from the multivariable logistic regression model including all patients are depicted in Table 2. Notably, after adjusting for important covariates, the association of epidural analgesia with occurrence of UTI persisted (OR 1.59 [1.35–1.89]; $P < 0.001$). Other important variables associated with UTI included: age >70 (OR 1.23 [1.04–1.45]; $P = 0.02$), male gender (0.35 [0.29–0.41]; $P < 0.01$), ASA class ≥ 3 (OR 2.53 [1.00–6.41]; $P = 0.05$), COPD (OR 1.56 [1.12–2.17]; $P = 0.01$),

Table 1 Baseline and clinical characteristics of patients having liver or pancreatic operations, classified by use of epidural catheter ($N = 28,571$)

Characteristics	All ($N = 28,571$)	Epidural ($n = 5764$; 20.2%)	No Epidural ($n = 22,807$; 79.8%)	P-value
Median age (25th, 75th percentile)	63 (53, 71)	63 (55, 71)	63 (53, 71)	<0.01
Age > 70	28.5%	29.1%	28.3%	0.26
Male	49.4%	49.7%	49.3%	0.63
Race				
White	72.4%	68.9%	73.3%	<0.01
Black	8.6%	6.9%	9%	
Other/Unknown	19%	24.2%	17.7%	
Hispanic	5.3%	4.9%	5.3%	0.2
ASA score 3–5	72.7%	73.9%	72.5%	0.04
Smoking	17.1%	17.6%	16.9%	0.17
Diabetes	21.6%	21.6%	21.6%	0.7
Steroid use	3.1%	2.9%	3.1%	0.57
COPD	3.7%	4.0%	3.6%	0.13
CHF	0.4%	0.4%	0.3%	0.27
Bleeding disorder	2.9%	2.0%	3.1%	<0.01
Disseminated cancer	21.1%	20.1%	21.4%	0.04
Functional status:				
Dependent	0.6%	0.45%	0.7%	<0.01
Pancreatic surgery	59.2%	22.1% ^a	77.9% ^a	0.07
Liver surgery	40.8%	17.4% ^a	82.6% ^a	

Percentages represent proportions within corresponding column category unless otherwise specified.

Where COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure.

^a Percentages represent proportions within row category.

Table 2 Multivariable logistic regression model of postoperative UTI ($N = 28,571$)

Predictive variables	Multivariable analysis		
	OR	95% CI	P-value
Epidural use	1.59	1.35–1.89	<0.01
Male gender	0.35	0.29–0.41	<0.01
Pancreatic surgery	1.25	1.06–1.47	0.01
Age > 70	1.23	1.04–1.45	0.02
ASA score			
1 (vs. 0)	1.26	0.51–3.11	0.61
2 (vs. 0)	1.74	0.71–4.24	0.23
3–5 (vs. 0)	2.53	1.00–6.41	0.05
Smoking	0.76	0.60–0.95	0.02
Steroid use	1.25	0.85–1.83	0.26
COPD	1.56	1.12–2.17	0.01
CHF	2.61	1.23–5.52	0.01
Bleeding disorder	1.43	0.96–2.13	0.08
Functional status	2.44	1.37–4.35	<0.01

Where COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure, OR, odds ratio, CI, confidence intervals. Model performance: ROC = 0.68; Hosmer–Lemeshow = 6.27.

CHF (OR 2.61 [1.23–5.52]; $P = 0.01$), smoking (OR 0.76 [0.60–0.95]; $P = 0.02$), functional dependence (OR 2.44 [1.37–4.35]; $P < 0.01$), and pancreatic operations (OR [1.06–1.47]; $P = 0.01$).

Gender- and age-specific analysis

To better examine the difference in the contribution of epidural use on UTI based on gender and age, univariable and multivariable regression models were stratified by gender. In general, UTIs were more common in females (3.5% vs. 1.3%; $P < 0.001$). Similarly UTIs were more frequent in the elderly group (≥ 70 years) (3% vs. 2.2%; $P < 0.001$). These results are best illustrated in Fig. 1. Importantly, the use of epidural analgesia was associated with increased risk of UTI in univariable and multivariable analysis for both males and females (MV analysis: OR 1.41 [1.02–1.97]; $P = 0.02$, and OR 1.65 [1.35–2.01]; $P < 0.01$, respectively). Notably, for male patients, increasing age (age > 70) was a strong predictor of UTI (OR 1.91 [1.41–2.59]; $P < 0.01$), while the strength of this association disappeared for females (OR 1.12 [0.92–1.36]; $P = 0.27$). Risk estimates for UTI based on bivariable analysis of age and gender in patients with and without epidural is illustrated in Fig. 2.

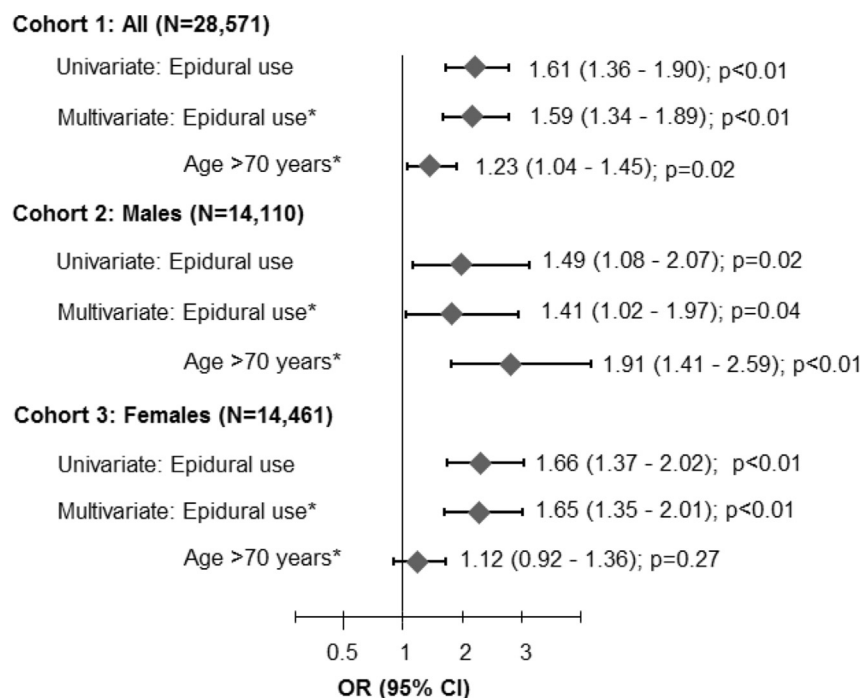
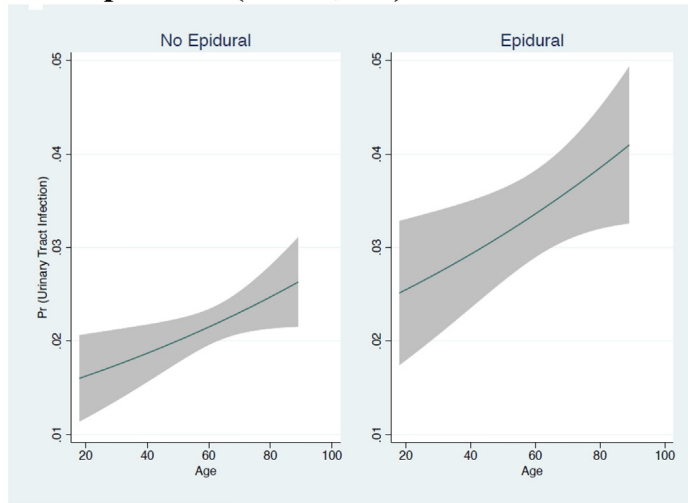
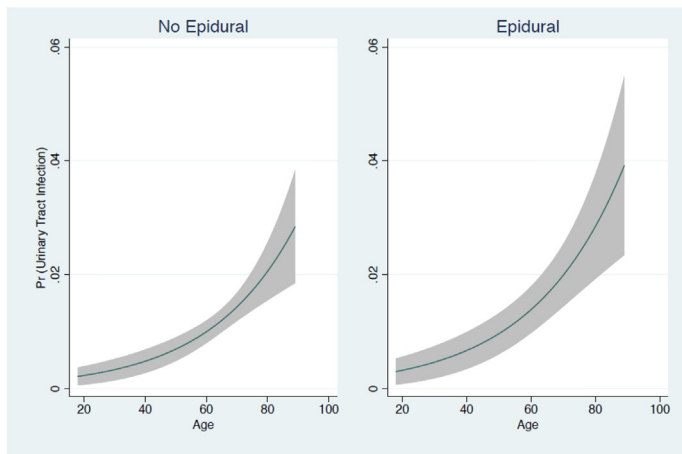


Figure 1 Univariable and multivariable logistic regression models for postoperative UTI examining the association of use of epidural catheter and age, with stratification by gender. *Multivariable analyses adjusted for baseline demographic and clinical characteristics. Where OR, odds ratio, CI, confidence intervals

a) All patients (N= 28,571)



b) Male (n= 14,110)



c) Female (n=14,461)

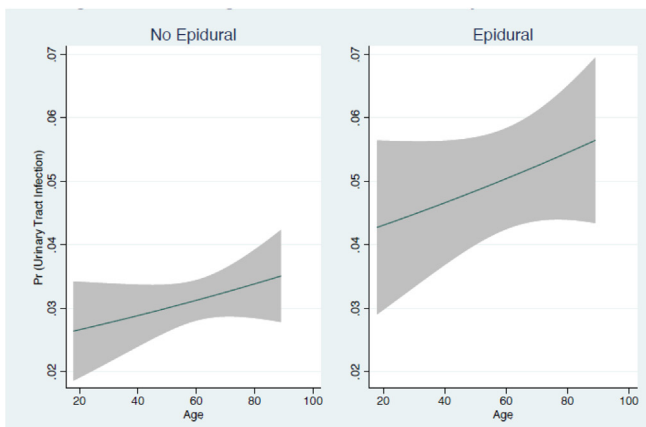
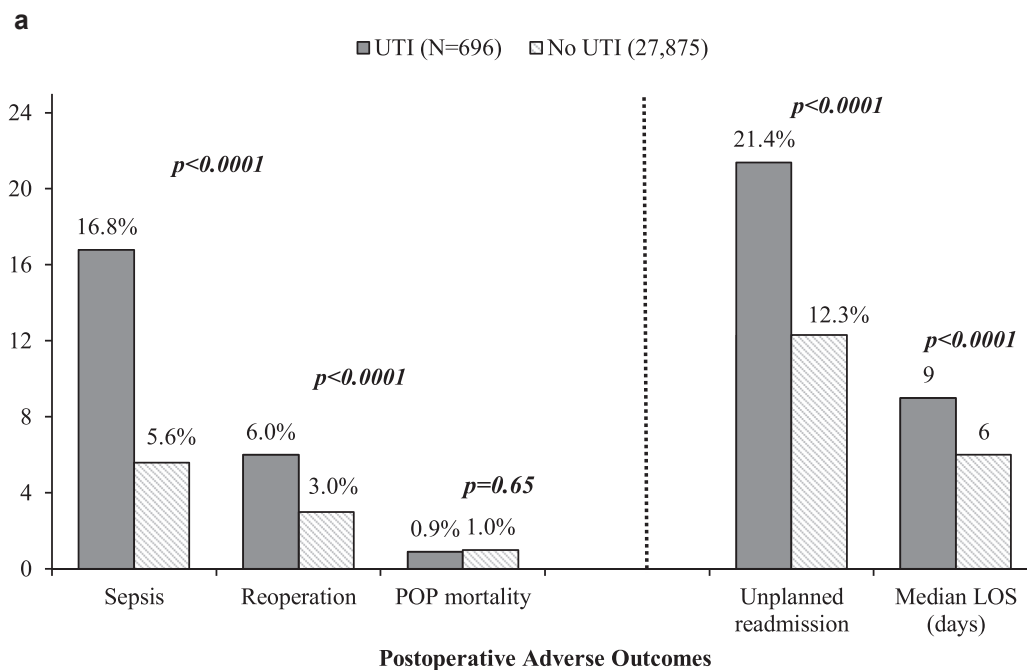


Figure 2 Risk estimates of postoperative UTI with 95% confidence intervals by age, in patients with and without epidural in the whole cohort (a), and by gender: males (b) and females (c)



b

Adverse event / secondary outcome	Odds ratio [95% confidence interval]	P value
Sepsis	3.44 [2.77-4.26]	<0.001
Reoperation	0.78 [0.29-2.08]	0.62
Postoperative mortality	0.84 [0.31-2.25]	0.72
Unplanned readmission	2.09 [1.75-2.5]	<0.001
Median (LOS)**	2.42 [2.06-2.78]	<0.001

*Multivariable regression models adjusted for: age, sex, ASA status, functional status, COPD, CHF, steroid use, smoking status, surgery type, cardiac arrest, unplanned intubation, post-operative cardiac event.

**Linear regression model adjusted for the same variables. UTI was associated with an overall 2.42 day increase in LOS.

Figure 3 Association of postoperative UTI with other postoperative adverse outcomes (N = 28,571)

Secondary outcomes

Univariable and multivariable analysis were performed to examine the impact of UTI occurrence on other adverse outcomes. UTI was associated with a statistically significant higher rate of postoperative sepsis (16.8% vs. 5.6%; $P < 0.01$), and reoperation (6% vs. 3%; $P < 0.01$). No difference was seen in overall rates of postoperative mortality (0.9% vs. 1%; $P = 0.65$), however there was higher need for postoperative healthcare

resource utilization in patients with UTI as described by a higher rate of unplanned readmissions (21.4% vs. 12.3%; $P < 0.01$) and increased median LOS (9 days vs. 6 days; $P < 0.01$). On multivariable analysis, UTI was associated with increased risk of postoperative sepsis (OR 3.44 [95% CI 2.77–4.26]), unplanned readmission (2.09 [1.75–2.50]), and median LOS (linear regression – coefficient 2.42 days [2.06–2.78]) (Fig. 3).

Discussion

Using a nationally validated, risk-adjusted, outcomes-based database we found that patients undergoing hepatopancreatobiliary operations and treated with perioperative thoracic epidural analgesia had an increased risk of postoperative UTI. Interestingly, only 20% of patients utilized TEA – despite established recommendations. Patients receiving TEA were more likely to have a UTI, with a higher risk with increasing age for the male population. Importantly, as previously published for different settings,^{17–19} the clinical impact of UTI occurrence was significant, with higher risk of related adverse events: patients with UTI had higher rates of sepsis (16.8% vs. 5.6%) and higher healthcare utilization represented by increased unplanned readmissions (21.4% vs. 12.3%) and longer length of hospital stay (9 days vs. 7 days). Further, after adjusting for important variables, UTI was associated to increased risks of postoperative sepsis and unplanned readmission, as well as an overall increase in median LOS.

Among the salient findings from our analysis was the association of UTI with TEA utilization for the whole population. Although to some extent intuitive, this association has not been previously described in the context of ERAS pathways and in particular for the HPB population. The majority of studies showing this relationship thus far involve the postpartum population using epidural analgesia for labor.²⁰ A number of studies in different settings however, have documented the association of TEA and urinary retention, ranging 14–33%.^{21,22} Based on such observations it is not uncommon – in fact it is frequently described as *common practice* – to maintain the urinary catheter in place until the epidural catheter is removed. Our results cannot point towards the specific mechanism by which TEA leads to increased rate of UTI, and if this finding is directly related to the neurologic bladder blockade resulting from TEA,^{13,23} the need for reinsertion of indwelling urinary catheters when urinary retention occurs,²⁴ or a consequence of prolonged bladder catheterization in current practices (including within ERAS framework).²¹ Nevertheless, despite documented risk of urinary retention, there is significant data supporting the early removal (within 24–48 h of surgery) of the bladder urinary catheter in patients with TEA, and how this practice is associated with overall improved outcomes following abdominal operations, including decreased rate of UTI, and lower readmission rates and overall length of hospital stay.^{25–27} With TEA considered among a “best-practices” option, future work must strive to understand the mechanisms leading to increased UTI with TEA, and work to facilitate implementation of evidence-based urinary catheter removal protocols, which should become a discrete domain within ERAS pathways.

One of our primary goals was to examine the differential effect of TEA on UTI by gender and age, with special focus on the male elderly population. Interestingly and in line with our hypothesis, we found that despite TEA utilization being associated with UTI in both males and females – for male patients, there was a

significant incremental risk with increasing age, with the steep inflection point at the 60–70 years mark (Fig. 2b). This finding supports prolonged bladder catheterization and urinary retention as important mechanisms leading to UTI, as these circumstances are both more frequent in older males. With liver and pancreatic cancers presenting preferentially in older adults, and median age at presentation of up to 71 years,²⁸ perioperative interventions need to be tailored for this population. This is particularly relevant in the current context, as the use of epidural analgesia continues to increase when compared to prior practices (7.4%–20%),¹⁰ and with other pain control strategies having emerged and found to be at least equally effective or potentially better.

Several studies have shown the implementation of indwelling catheter protocols to significantly reduce UTI in surgical patients.^{29–31} When TEA is used for perioperative analgesia in patients having HPB operations, such protocols and/or initiatives must become part of the ERAS framework, to maximize the benefits of epidural analgesia while minimizing the side effects derived from non-standardized TEA use. Similarly, recent studies have shown important benefits of alternative perioperative analgesia strategies, including the use of transversus abdominis muscle infiltration (TAP block) with long-acting local anesthetic – liposomal bupivacaine, and findings of equally effective pain control to TEA, and lower overall opiate utilization and costs.^{32–34} Other strategies including intrathecal analgesia and multimodal pain treatment including continuous infusion wound catheters have also emerged as appropriate alternatives.^{35,36} When considering the use and benefits of one strategy over the other it is critical to understand and measure secondary outcomes associated with the use of TEAs; despite potential side effects of epidural analgesia (e.g., postoperative hypotension, bleeding and infection), the benefits in relation to decreasing cardiopulmonary complications for the most vulnerable population are noteworthy.³⁷ As the development and implementation of ERAS pathways continue to evolve, perioperative analgesia must include details that describe appropriate utilization of each strategy (i.e., including urinary catheter management) and that give room for studying and implementing tradeoffs of using alternative strategies.

This study has several limitations. First, we did not have data on the utilization, duration and removal of urinary bladder indwelling catheters and the differences that may exist between institutional practices. However, our findings represent the association between TEA utilization and UTI in the context of real-world practices with high generalizability. Studies explicitly evaluating the contribution (or confounding effect) of urinary catheter management in the setting of TEA would help to better characterize the association and further support efforts to facilitate implementation of urinary catheter removal protocols, as quality improvement projects geared to improve current care. Similarly, given the retrospective nature of the study, there are limitations related to selection bias.

However the prospective nature of ACS-NSQIP as well as the robust data on clinical, quality and outcome-based variables helps offset these limitations to some extent. Further, with the current available data, future work should focus on prospective evaluation of different perioperative pain management strategies, which can help minimize selection bias while also examining the efficacy of different protocols in day-to-day practices.

In summary, results from this analysis showed that TEA is a common practice for perioperative pain control in elective HPB operations. However, most patients still do not receive an epidural catheter, with a clear opportunity to implement evidence-based approaches for adequate pain control. Given the association of TEA and UTI, and the incremental risk observed in elderly male patients, efforts must focus on rigorous adherence to best-practice urinary catheter removal guidelines,³¹ as a key process within the ERAS framework. Similarly, when considering pain control options for patients at increased risk of TEA-related adverse events (vulnerable elderly population, males), more novel strategies, such as TAP blocks with liposomal bupivacaine, can provide effective results, with lower morbidity and costs – and should be studied and strongly considered as a first-line alternative, in the right context.

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Conflicts of interest

The authors declare no competing interests.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.hpb.2020.04.013>.