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Outcomes and costs analysis of Externalized PyeloUreteral versus internal Double-J ureteral stents after paediatric laparoscopic Anderson-Hynes pyeloplasty.

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Outcomes and costs analysis of Externalized PyeloUreteral versus internal Double-J ureteral stents after paediatric laparoscopic Anderson-Hynes pyeloplasty.

SUMMARY:

Background: The gold standard treatment for Uretero-Pelvic Junction Obstruction (UPJO) is laparoscopic dismembered pyeloplasty according to the Anderson-Hynes technique. The internal Double-J ureteral (DJ) and the Externalized PyeloUreteral (EPU) stents are usually the drainage of choice. Only a few articles have compared the clinical impact of the different drainage techniques on the perioperative morbidity and none presented a cost analysis of the incurred hospital stay.

Objective: To present the clinical outcome and financial analysis of a cohort of children who underwent a laparoscopic pyeloplasty comparing the use of the DJ versus EPU stent.

Study design: Retrospective study of consecutives children who underwent laparoscopic Anderson-Hynes pyeloplasty in a single tertiary paediatric referral centre from January 2017 to March 2020. Patients were grouped according to the type of stent used: DJ stent vs EPU stent.

Results: Fifty-three laparoscopic pyeloplasties were performed on 51 patients: 27 (50.9%) had an EPU stent and 26 (49.1%) a DJ stent. There was no statistically significant difference between the two patient groups with regards to surgical time, hospital stay, stent-related complications or the need for re-do surgery. All the EPU stents were removed with an outpatient admission 8.1 days ± 3.1 after surgery while the DJ stents were removed with a cystoscopy 61.6 days ± 30.2 after surgery (p value < 0.001). On a financial analysis (Figure), the hospital costs for stent removal were significantly lower for the EPU stent group (£ 686.7 ± 263.4 vs £ 1,425 ± 299.5, p value < 0.01).

Discussion: Both drainage methods have some disadvantages. Possible complications associated with DJ stents include migration and artificial vesicoureteric reflux which may lead to higher incidence of Urinary Tract Infections. Possible disadvantages of the EPU stent insertion are related to the damage of the renal parenchyma and to the risk of developing skin site infections and urinary leaks. However, in our series the EPU stent has not been associated with a higher incidence of bleeding, leakage or discomfort. In addition to

clinical considerations, there is a financial implication to be considered. With this regard, the EPU stent was associated with a significant reduction in the incurred hospital costs.

Conclusions: The use of DJ and EPU stents is equivalent in regards of overall complications and success rates. DJ and EPU stents provided comparable success and complication rates, however the latter avoids the need of an additional general anaesthesia and reduces the overall incurred hospital costs.

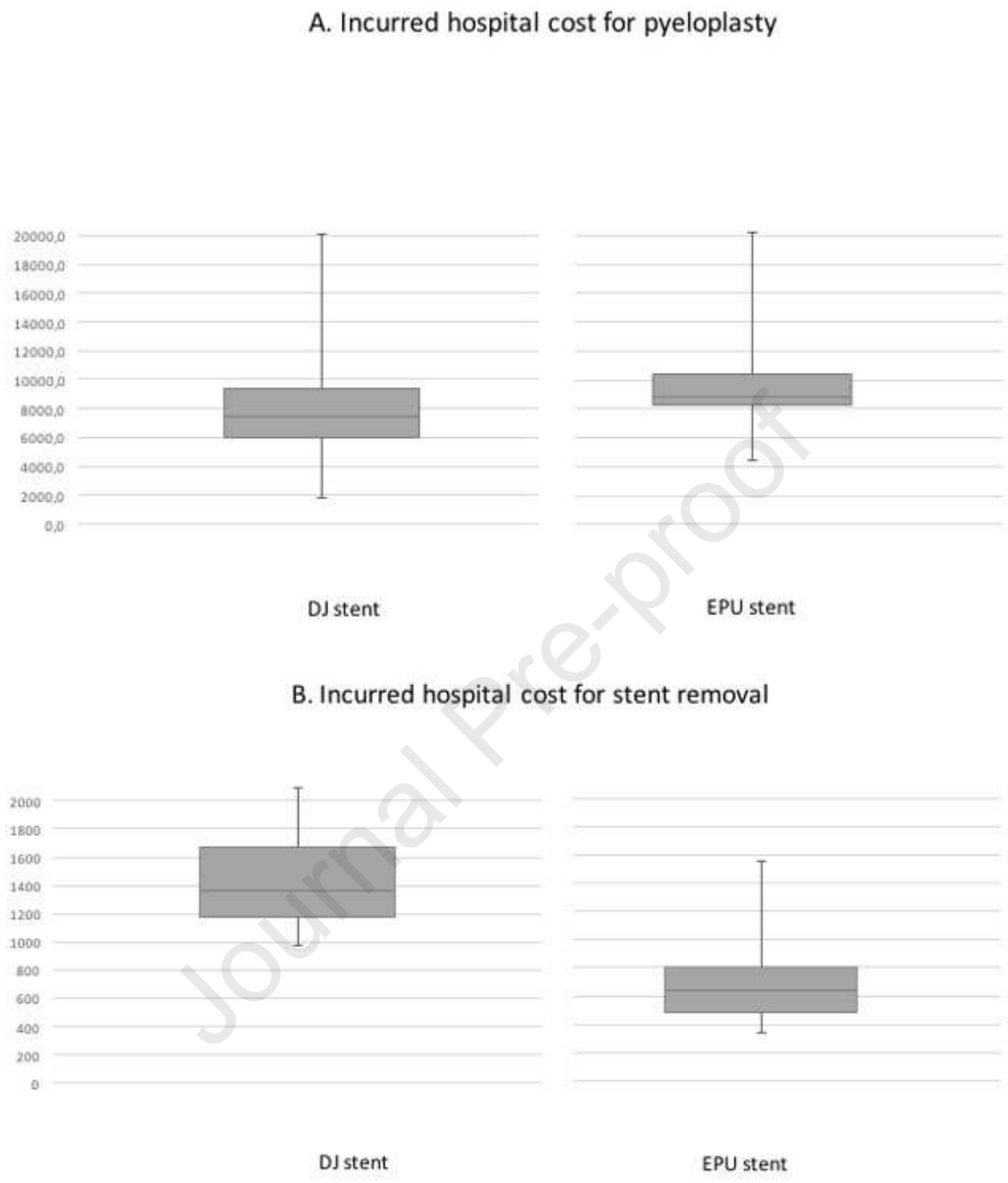

Fig 1. Comparison of incurred hospital costs (British pounds sterling) between DJ stent and EPU stent for pyeloplasty (A) and stent removal (B).

Key words: ureteropelvic junction obstruction (UPJO), laparoscopic pyeloplasty, ureteral stent, cost analysis

Introduction

Uretero-Pelvic Junction Obstruction (UPJO) is the most common congenital abnormality of the upper urinary tract, with an incidence of 1 in 1500 live births [1]. With increased use and sensitivity of ultrasound scan, the antenatal diagnosis of hydronephrosis has increased, accounting for approximately 1–5% of all pregnancies [2]. In 10–30% of cases, hydronephrosis is caused by UPJO and approximately 20-50% of those children eventually require a surgical intervention [3-4].

Since the first description in 1995 [5], ~~laparoscopic~~ Anderson-Hynes dismembered pyeloplasty has become the gold standard for the surgical treatment of UPJO in many centres~~,~~ and is carried out with either an open or a minimally invasive approach ~~combining the safety and the efficacy of the open approach with the advantages of the minimally invasive procedure~~ [6-8].

Although some authors [9-10] have described excellent outcomes (in favourable cases) of unstented laparoscopic pyeloplasty, most surgeons still prefer stenting the newly formed anastomosis.

To date, several methods of postoperative renal drainage have been described both for open or minimally invasive procedures performed in children, the most common being the insertion of an internal Double-J ureteral stent (DJ) [9-13] or an Externalized PyeloUreteral (EPU) stent [9,10,12-17].

Only a few articles have compared the clinical impact of the different drainage techniques on the perioperative morbidity [9,10,12,13] and none presented a cost analysis of the incurred hospital stay.

In addition to clinical outcomes, in fact, evidence of cost-effectiveness in patient management is a recognized part of modern patient care and has an increasingly relevant role in the evaluation of treatments and pathways.

Our aim is to present the clinical outcome and financial analysis of a cohort of children who underwent a laparoscopic pyeloplasty comparing the use of the DJ versus EPU stent.

Patients and methods

This is a retrospective study of consecutives children who underwent laparoscopic Anderson-Hynes pyeloplasty in a single tertiary paediatric referral centre from January 2017 to March 2020.

The indication for intervention was based on the latest guidelines [18] and included impaired split renal function (less than 40%), decrease of split renal function of more than 10% in subsequent studies, increased anteroposterior diameter on the ultrasound and grade III and IV dilatation as defined by the Society for Fetal Urology [2].

Preoperative data (including gender, age and UPJO laterality), perioperative characteristics (operative time, intraoperative complications), postoperative data (such as complications, length of hospital stay, time of stent in place, stent-related complications, need for redo surgery) and incurred hospital costs for both admissions (pyeloplasty and stent removal) were recorded and analysed.

Patients were divided into 2 groups based onto the type of stent positioned (EPU versus DJ stent). The Clavien Dindo (CD) grading system was used to classify the severity of postoperative complications [19].

Surgical detail and stent positioning

All operations were performed using a trans-peritoneal approach; patients were placed in a lateral decubitus position with the table flexed to stretch the ipsilateral flank. At the time of the uretero-pelvic anastomosis, the choice of stent was based on operating surgeon preference.

For externalized stenting a 4.7 French nephrostomy stent was used (Urosoft Multipurpose Stent, Angiomed-Bard, Germany). Intraoperatively the double coiled multiperforated stent is modified by removing one coil, so it terminates in the mid-ureter. After half of the pyeloureteral anastomosis is completed, the nephrostomy stent is loaded on the back of a Kirschner wire (K-wire) 1.6 mm 250 mm (Ortho Solutions, UK) and introduced through the cranially placed working port under direct vision, guided through the open pelvis, into the posterior lower calyx and then through the renal parenchyma to emerge on the surface of the lateral abdominal wall (at the renal angle). [17] The externalized end is left on free drainage for 48 hours, then knotted before patient discharge and

covered under a dressing. At approximately 7 postoperative days, the stent is removed in an ambulatory setting with no need for sedation or GA.

DJ stent (Percuflex™ Plus ureteral stent set) was typically 4.8-French in diameter and was placed in an antegrade fashion. Stents are usually left in situ for 6-8 weeks and removed during a cystoscopy under GA.

~~Treatment success was defined as improvement in symptoms and/or hydronephrosis grade.~~

Follow-up included renal tract ultrasound scan (USS), MAG-3 study and outpatient clinic consultation.

Treatment success was defined as improvement in symptoms and/or hydronephrosis grade as confirmed by postoperative USS (performed at 3 and 12 months post-surgery) and improvement in the drainage as confirmed by the post-operative MAG-3 study (performed at around 9-12 months after the operation).

Cost Analysis

The financial data was provided from our institution's patient level costing system. This system reports the costs incurred by a patient through their hospital stay.

The economic outcome was calculated as the direct costs associated with the two hospital admissions (pyeloplasty procedure and removal of the stent).

Statistical analysis

Continuous normally distributed indicators were compared with two-sample t-tests. Categorical and continuous non-normally distributed indicators were compared with the Pearson's chi-squared tests and the Mann□Whitney U test respectively. The calculations were performed using QuickCalcs – GraphPad Software.

Results

In the study period, a total of 53 laparoscopic pyeloplasties were performed in 51 patients (26 females; 25 males) (1 patient had interval bilateral procedures, 1 had a laparoscopic re-do surgery). In 27 (50.9%) cases the kidneys were stented using an EPU stent while in the remaining 26 (49.1%) using a DJ stent.

Patients' demographics, outcomes and complications are summarized in Table 1 and in Table 2, respectively.

Patients having an EPU stent inserted were significantly younger (58.8 months ± 56.0) in comparison with those who have received a DJ stent (107.2 months ± 53.0) (p value < 0.01).

Surgical time (209.1 min ± 36.4 vs 225.3 min ± 77.2), length of hospital stay (2.6 days ± 1.4 vs 2.3 days ± 1.2), length of follow-up (26.3 months ± 8.2 vs 31.4 months ± 8.4), occurrence of stent-related complications (11.1% vs 15.4%), need for re-do surgery (0.0% vs 7.7%) were not statistically different between the two groups.

A total of 7 stent-related complications, occurred in the immediate postoperative period. 2 Clavien-Dindo grade I: 1 occurred in the EPU stent group (the formation of a blood clot obstructing the urinary flow through the uretero-pelvic junction) and 1 in the DJ stent group (a debilitating abdominal pain associated with haematuria requiring additional analgesics); 3 Clavien-Dindo grade II: 1 occurred in the EPU stent group (a wound infection at the site of the stent insertion requiring systemic antibiotic administration) and 2 in the DJ stent group (recurrent urinary tract infections requiring systemic antibiotic administration); 2 Clavien-Dindo grade IIIb: 1 occurred in the EPU stent group (a postoperative stent displacement requiring the positioning of a DJ stent under general anaesthesia) and 1 in the DJ stent group (a child who developed a severe ipsilateral ureteral dilatation due to a stent misplacement which didn't reach the bladder as a consequence of an unrecognized uretero-vesical junction (UVJ) obstruction and therefore required a UVJ balloon dilatation and retrograde stenting on postoperative day 4).

One child (in the EPU stent group) developed a non-stent related postoperative complication and required a laparotomy on day 4 postoperative for an incarcerated hernia at the site of the umbilical

incision.

The EPU stents were removed after a mean period of 8.1 days (± 3.1), without any complications, while the DJ stents were removed after 61.6 days (± 30.2) (p value < 0.001) with a cystoscopy under general anaesthesia as a day-case procedure.

The procedure was successful in all patients in the EPU group while 2/26 (7.7%) children in the DJ stent group required a further intervention due to recurrent abdominal pain and worsening pelvic dilatation.

The procedure charges were sub-analysed to consider the cost of the primary pyeloplasty and the cost of the subsequent admission for stent removal.

When considering the incurred hospital costs for pyeloplasty alone, there was no statistically significant difference between the two groups of patients (EPU stent group £ 9,620.2 ± 3,746.5 vs DJ stent group £ 8,346.6 ± 4,133.9; p value 0.5459).

Considering the admission related to the stent removal, the costs for patients in EPU stent group were significantly lower in comparison with the DJ stent group (EPU stent group £ 686.7 ± 263.4 vs DJ stent group £ 1,425.6 ± 299.5 vs; p value < 0.01).

Interestingly, the reimbursement for laparoscopic pyeloplasty, under the National Tariff Payment System (NTPS https://improvement.nhs.uk/resources/national-tariff/), did not to cover the hospital costs for a majority of patients (average tariff: £ 7,067.91).

Discussion

To the best of our knowledge, this is the first study that has explored and compared surgical outcomes and cost analysis of the use of DJ versus EPU stents in draining the renal pelvis following laparoscopic pyeloplasty in children.

Dismembered Anderson-Hynes pyeloplasty performed via open or minimally invasive approach is the gold standard technique for the surgical treatment of UPJO in children [6-8], but there is still ongoing controversy regarding the best postoperative drainage technique.

Even though some authors [9-10] have described the safety and the efficacy of unstented laparoscopic pyeloplasty associated with or without a perinephric drain and a bladder catheter, the majority of surgeons prefer to leave a trans-anastomotic stent to drain the renal pelvis. The aim is to release the stress on the newly formed anastomosis as well as to prevent the risks of developing immediate postoperative obstruction due to tissue oedema.

The most commonly reported types of urinary diversions used after minimally invasive pyeloplasty in children include the internal DJ stent [9-13] and the EPU stent [9,10,12-17,20,21]. The former can be inserted in an antegrade or retrograde fashion [22] and, generally, needs retrieval by cystoscopy. The latter exit the kidney through the renal parenchyma [15,16] or the renal pelvis [12, 14, 20, 21] and allows stent removal on an outpatient basis.

Although the two types of stent share the common risks of having in situ a foreign body (such as bleeding, infection and patient discomfort), each carries its own pros and cons.

Other factors that should be taken into consideration also include the reliability of the technique used for stent insertion, the ease of its positioning and the operative time required for its placement, especially during the more technically demanding minimally invasive procedures performed in small children.

The placement of a DJ stent across the Uretero-Vesical Junction (UVJ) can potentially be difficult and cause UVJ trauma, especially in small infants, with a failure rate of up to 3.3% (n=2/61) in the series reported by Ninan et al.

Although some articles report a significantly longer operative time for minimally invasive DJ stent insertion [9], this has not been confirmed by this or others studies [12,13].

Possible complications associated with DJ stents include migration, breakage, encrustations, stone formation and occlusion. DJ stent malposition can cause serious problems, as demonstrated by the case we had observed in our series. In a series of 55 patients reported by Elmalik et al, 3 (5.5%) DJ stents migrated into the bladder and 2 (3.6%) into the upper urinary tracts. Helmy et al [12] recorded the case of a DJ stent dislodgement into the posterior urethra in a child who experienced

lower urinary tract symptoms while Chu et al's comparative study [13] reported a higher occurrence of DJ stent dislodgement (n=2/44 (4.5%) compared to none/17 (0.0%) of EPU stents after robotic-assisted laparoscopic pyeloplasty.

Moreover, the use of a DJ stent could cause an artificial vesicoureteric reflux and has been associated with higher incidence of Urinary Tract Infections (UTI) and pyelonephritis in the series reported by Kocvara et al [9] and by Chu et al [13]. In our population this trend was confirmed, with 2/26 (7.7%) children in the DJ group versus 0/27 (0.0%) children in the EPU group developing postoperative UTIs.

An extreme (and rare) complication of the insertion of a DJ stent has been described by Kocvra et al [9] who reported the case of a boy in whom the DJ stent was inadvertently inserted into the opposite ureteric orifice during the antegrade positioning causing contralateral partial ureteric obstruction, raise in creatinine and urinary leakage.

Finally, there are reports of DJ stents that have been forgotten and remained in situ for many years. [23]

As opposite, the use of the EPU stent avoids bladder-related complications, such as UVJ traumas, gross haematuria or bladder spasms. In Chu et al's series [13] 11/44 (25.0%) patients undergoing a DJ stent insertion versus 0/17 (0.0%) undergoing a EPU stent insertion experienced gross haematuria (p value = 0.03).

The most commonly believed disadvantages of the EPU stent insertion are related to the damage of the renal parenchyma and to the risk of developing more skin site infections and urinary leaks [13]. However, neither in our series, nor in published comparative studies the EPU stent has been associated with a higher incidence of bleeding, persistent urinary leakage, skin infection or discomfort [9,12,24].

Furthermore, the EPU stent has the advantage of being accessible and, in case of suspected early complication such as urinary leak or blockage or co-existing UVJ obstruction, it can be both unknotted and used as nephrostomy drainage or used to perform an anterograde nephrostogram

study.

We have not found any difference in length of hospital stay either in our cohort or in published articles [12,13,24].

In spite of a higher occurrence of surgical failure in the DJ stent group (DJ stent group: n=2/26, 7.7% vs EPU stent group: n= 0/27, 0.0%) the operative success did not seem to be affected by the type of stent chosen (p value 0.2358) [12,13,24].

Thus, the main benefit of the use of EPU stent is that it obviates the need of a second procedure performed under general anaesthetic for its retrieval with its (although minimal) possible associated complications. Reducing the number of anaesthetics a child receives is likely to beneficial, particularly when considering that recent literature hasn't excluded the risk of neurotoxicity and cognitive delays in early infants undergoing repeated anaesthetics [25,26].

Although alternative approaches have been proposed for DJ stent retrieval without the need of GA, their advantages and drawbacks have yet to be fully determined. For example, the use of a dangler string attached to the DJ stent may increase the overall operative time, requiring a preoperative cystoscopy for stent insertion and patient repositioning. The presence of the proximal coil of the stent in the surgical field can make more difficult to perform the ureteropelvic dismemberment and anastomosis [27]. Other disadvantages of the DJ stent with a dangler may include a higher risk of early stent dislodgment outside of the renal pelvis, string migration into the urethra, urethral discomfort, urethral lesion or a higher occurrence of lower urinary tract symptoms (such as bleeding, urgency, frequency or infection).

The use of magnetically tipped ureteral stents for pyeloplasty is still limited in the paediatric population [28,29] and never described after the minimally invasive approaches.

In addition to clinical considerations, there is a financial implication to be considered.

With this regard, our study demonstrated that the EPU stent was associated with a significant reduction in the incurred hospital costs. This confirmed the findings of other authors regarding open pyeloplasty [30].

For a majority of patients, the hospital costs were higher than the level of reimbursement for laparoscopic pyeloplasty. This study (and others like this) could be the trigger for reducing cost variation and engaging in open dialogue with commissioners because is essential to ensure sustainability.

In timings of financial constraints, when the search for cost-effectiveness of medical treatments is paramount, clinicians must consider all possible way to save money without jeopardising patient's safety or clinical outcomes. In our series, hospital costs for DJ stent removal have been more than double those for EPU removal (£ 1,425.6 ± 299.5 vs £ 686.7 ± 263.4, p value < 0.01).

There are limitations to our study. The retrospective nature carries potential bias, such as a relatively small cohort, patient selection and operator preferences. Furthermore, at baseline our groups were heterogeneous, with the patients in the EPU group being significantly younger (this, however, is coincidental and the difference in use of stent was operator dependent rather than patient-related). Despite the younger age, however, the safety and efficacy were similar for both types of stent, without any additional postoperative complication.

Conclusion

Our study suggests that DJ and EPU stents positioned during laparoscopic Anderson-Hynes pyeloplasty are equivalent with regards to operative time, length of hospital stay, overall complication and success rate. However, the insertion of the EPU stent obviates the need of a following GA, lowering operative risks and hospital costs.

Conflicts of interest/Competing interests: None

Research involving Human Participants and/or Animals: Retrospective research

Informed consent: N/A

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