8-21-2009

Are Urinary Catheters Necessary During Endovascular Procedures? A prospective randomized pilot study

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Medical Student Research Project

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Introduction

Background

The use of urethral catheterization in surgery can trace its root to 19th century military surgeons utilizing them to prevent urinary retention after morphine use, and to minimized complications after spinal cord injury [1]. It has become a common surgical practice to place urinary catheters in patients during many interventions [2, 3]. This practice has little support in evidence based literature [4, 5]. In theory a urinary catheter is place to drain the bladder and avoid complications such as over dilatation of the bladder which may result in dystonia [2, 6]. These complications are not well demonstrated in their occurrence and have been poorly examined in short procedures, defined here as those interventions planned to take less than six hours [5, 7].

Urethral Catheterization and its complications

Inserting a catheter involves the use of sterile technique, as the person cleans the urethral meatus and surrounding structures, in order to insert the catheter in a sterile environment. Then a lubricated catheter is inserted into the urethra and is advanced past the sphincters until it is in the trigone area of the bladder. A balloon around the catheter is then inflated with saline to maintain placement. The catheter has an open end and is then connected to a bag for drainage [8]. This common pre-operative protocol has many steps and thus many points for complications to occur or for the introduction of pathogens. The exact rate of infection from insertion alone is not known exactly, but has been estimated to be as high as 14-27% per hospital stay if a catheter has been used , when urinary tract

infection (UTI) is defined as greater than 10^5 colony forming units and/or symptoms consistent with a UTI [9]. It is known that urinary catheters do put a person at increased risk for infection and bacturia, which is observed as a rate of about 4-7% pre day a catheter remains in place [10]. These rates were found in all comers who were had a urinary catheter placed. The actual rate is surgical patients may be higher as the post-operative period is an immunocompromised state [11, 12]. Mechanical trauma can occur on insertion of the catheter, allowing a port of entry for bacteria [13]. Though some complications may be avoided with antibiotic use, there are no data in the literature to support the routine use of antibiotics for prevention of infectious complications when using a Foley catheter. In addition, drug resistance in urinary tract organisms is common and may promote a more serious infection[9, 12].

Why urinary catheters are used.

A major reason why urinary catheterization is used is to prevent or aid in the treatment of urinary retention after the patient is anesthetized and to monitor hydration status [4, 11]. The risks for developing urinary retention were found to be increasing age, anorectal procedures, use of spinal anesthesia[4], and procedures longer than six hours [6]. In addition to its role in lowering the risk of certain complications, Foley catheters minimize bladder volume and thus help maximize space for abdominal procedures [3]. Another rare complication worth mentioning is acute renal failure. If micturation cannot be accomplished in a person who already has impeded renal function, a post –renal obstructive acute renal failure may present most notably risk in diabetic patients [6]. These patients may also developed acute renal failure, and this case the catheter is

indicated to monitor urine output during surgery. This is more validated in long, highly invasive procedures [6].

Review of Current Practice

In current practice, there are many procedures, especially those shorter that 6 hours, where many surgeons do not insert a urinary catheter [14]. Additionally, some surgeons only insert a catheter in the post-operative period if the patient is unable to void [15]. It is possible in current practice that urinary catheters are overused and pose unneeded infectious risks [5]. In one clinical review, the authors conclude that catheters must be used sparingly and should only be used when antimicrobial engineering precautions are taken and when proper technique is used and there is an absolute indication, such as those described above [5].

Review of data regarding necessity of catheter use

There are very few studies that review the need for or the use of urinary catheters during surgical procedures. One such review studied the need for catheterization in laparoscopic cholecystectomies. This trial showed that in this procedure there is a reduction of cost and no change in outcome or catheter related complication rate if the Foley catheter was omitted [16]. Similarly, in two nearly identical non-randomized prospective studies involving orthopedic operations, the authors looked at overall infection rates in patients with universal pre, intra and post operative catheterization versus catheterization only as needed post-operative. They concluded there was no significant difference in infections, but noted a $400- $600 saving if catheterization was done on an as needed basis [14, 15].

Unfortunately, this is a thorough sampling of the few studies in this area; none are randomized and all examine a single procedure. Thorough detailed reviews and meta-analyses in this area are also lacking.

Justification for this study

Few high quality evidence based studies examine the use of urinary catheters in surgical procedures, and catheters are commonly inserted pre-operatively. Our study would examine the use of Foley catheters with endovascular procedures. There is also a debate in the literature which type of urinary catheter is needed, and if they are needed at all in uncomplicated patients, as such we will examine the confounding factors in patients being examined.

Methods

A randomized prospective control trial was be undertaken after IRB applications were approved by the University of New Mexico IRB. All portions of the study were carried out at UNMH.

Inclusion and Exclusion-

The study population consisted of endovascular patients on an intent-to-treat basis. All patients were non-emergent and male or female, undergoing endovascular procedures,

anticipated to be less than 4 hours and gived informed consent. These patient were all18 or older.

Subjects were excluded if there was an absolute requirement for a Foley catheter, such as urinary retention, chronic renal disease or other similar conditions, or those having long term placement of urinary catheter. Also patient with diagnosed BPH felt to be severe based on chart review were excluded.

Randomization -

A randomized sequence was generated by permuted blocks method (variable block sizes). The sequence was concealed in opaque sealed envelopes which were allocated to the patient after recruitment but only opened by the circulating nurse only after the patient is anaesthetized, blinding the patients and person evaluating and assigning envelopes to their assigned grouping. The nurse inserted or did not insert a catheter as directed by the randomized envelope and then the operation proceeded as normal. Only patients meeting all inclusion and having no exclusion criteria and giving informed consent were randomized.

Data collection-

All the data was collected by a single assessor. Patients' personal characteristics, history of UTI and urinary symptoms were collected using standard data form in the preoperative data collection. Urinary symptoms in the early postoperative period were recorded before discharge and if clinically indicated a urinalysis was done. At the first postoperative visit at one to two weeks later, patients will be questioned about urinary symptoms and if

clinically indicated a urinalysis was done. Outcome measures included requirement of catheterization in the non-catheterized group, bladder injury, postoperative catheterization, urinary symptoms, and UTI. Urinary symptoms include those which occurred in the early postoperative period (postoperative day 0 or day 1) and the late postoperative period (postoperative day 6 or day 7). UTI was defined as bacterial count greater than 10^5 colony forming unit per mL in the urine culture [7, 16]. To gage urinary retention bladder volumes via ultrasound or measurement of catheterized urinary volumes may be analyzed. Cost related to catheterization or non catheterization and its complications, including UTI rate, length of stay and adverse events including retention will also be recorded and analyzed.

Statistics:

Descriptive statistics will be utilized, including means, medians, modes and averages. Chi-square test with continuity correction will be used. The differences in the numerical data were compared using independent t-test. All data was analyzed using SAS 9.1 statistical suite.

Results

Demographics:

128 patients were eligible for the study, and of these 28 patients gave informed consent, and 21 patients meet all inclusion and had no exclusion criteria and were randomized. 11 patients were randomized to the no urinary catheter group, 10 were randomized to the

group receiving urinary catheter. One patient in the urinary catheter group did not show up for his operation, but remains in that data on as it is presented in intent to treat basis.

The average age in the no urinary catheter group was 55 year (Std dev=13.7) with a range of 26 to 76 years. In the urinary catheter group the average age was 65 (Std dev= 10.7) with a range of 48 to 79 years. The Z value is 1.8332 with a two-sided t approximation of 0.0817. In the no urinary catheter group there were 6 females and 5 males in the urinary catheter group there were 5 males and 5 females. None had pre-existing renal failure, severe BPH or other renal or urological issues, but 5 patients in the urinary catheter group and 6 in the no urinary catheter group had type 2 Diabetes Mellitus.

Interventions and Outcomes:

All patients were scheduled for vascular contrast fluoroscopy with or without endovascular intervention. The duration of the procedures on average was 150 minutes (std dev 97.2), the no urinary catheter average time was 127 minutes the urinary catheter group average was 173 minutes with $p<0.05$ between the groups. No patients died during their procedures, no patients suffered renal failure or urinary retention.

Of the patients enrolled in this trial 3 had events related to use or lack of use of urinary catheters. 4 people in the no catheter group and 5 in the urinary catheter group had clinically indicated urinalysis due to symptoms in the first two post-operative weeks. Of the 9 urinalysis performed, 8 were normal and 1 in the catheter group had a UTI. The 2 other events noted were patients who did not have urinary catheters placed during angiograms and due to clinical judgment of the surgeon had a catheter placed post-

operatively. The difference in complication rate regardless of type did not reach statistical significance with p=0.28.

Financial Outcomes:

Lastly, financial data was analyzed; the U.S. dollar amount recorded is based on the facility charge only and is exclusive of physician fee or special equipment not billed by the hospital. The average cost per procedure was $10900, with a range of $0 (the patient who was randomized but did not undergo an operation) to $22500. The average cost in the no urinary catheter group was $10540 and $11120 in the urinary catheter group. Based on itemized financial statement the average cost to insert a catheter is the urinary catheter group was $340 with a range of $325 to $475. The average cost to insert the post-operative catheters in the no catheter group was $242, averaged across the 11 no catheter patient to cost $41.25 per patient. Where the one UTI in the catheter group cost $1100 (inclusive of testing, antibiotics and follow-up), when group averaged across the 10 patients in the urinary catheter group cost $110 per patient. With a p value less than 0.05, thus reaching statistical significance.

Discussion

Urinary catheterization during endovascular procedures is not standardized at our institution and is largely dependent on the surgeon's impression of the patient and likely duration of the procedure. We found no major complications of urinary retention or renal

failure in the group who did not receive a urinary catheter in our patients undergoing relatively short endovascular procedures.

The two groups, who appear relatively similar in demographic criteria, though some large variances occur due to the small N, had statistically similar outcomes and complication rates over the small number of patients being analyzed at this phase of the study (n=1). But with an N value this low looking for relatively rare event we may see a significant difference if the studied continued to evaluate a larger number of patients. But we did find an unexpected event, in the non-catheterized group. In this group, 2 patients had post-operative catheters inserted by the surgeon as when post-operative anatomy was being examined after these patients received a relatively large IV volume of radio-opaque contrast, the bladder was visualized to be large and as these patients would have to lay flat for a number of hours the surgeon felt it necessary to provide bladder drainage for both patient comfort and to ensue the hemostasis would be maintained by patients remain flat.

One UTI was diagnosed in the group of 10 patients randomized to urinary catheterization; this corresponds to the above described rate of approximately 5-10% in the post-operative period. This complication was far more costly per incident described than those in that occurred in the non-catheterized group, lending some thought into another complication of use of urinary catheters in these endovascular cases.

The note able differences between the two groups can be seen in the financial outcomes data. The cost of their intervention averaged near $10000, but the insertion of a urinary catheter cost about $340 adding nearly 3% to the facility fee portion of the

intervention. Additionally, the cost of a catheter related urinary tract infection in the one occurrence was $1100, adding nearly 10% to the average facility charge for intervention.

Though the N of 21 in this early report of our trial we can begin to notes come trends. In non-acute, non-critical patient's underling diagnostic or therapeutic endovascular procedures, it is likely safe to operate with or without a urinary catheter in place. Additionally, in light of the expanding cost of medical service there is a significant increase in cost, 2-10% of the facility charge, in patients undergoing similar procedures with the main difference being intra-operative drainage of urine by Foley catheter.

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