The Effectiveness of Sterile versus Non-Sterile Urinary Catheter Insertion at Reducing the Incidence of Catheter Associated Urinary Tract Infection

A Systematic Review

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Dr. Josette Bettany-Saltikov

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Background

• Around 26% of hospital patients undergo urinary catheterisation:
  » To accurately monitor urine output
  » To treat urinary retention or incontinence
  » For investigation purposes


• Patients at a significant risk of acquiring a urinary tract infection;
  ▪ CAUTI (Catheter Associated Urinary Tract Infections) account for 45% of all hospital acquired infections


  ▪ 75% to 80% of all Healthcare associated UTIs follow the insertion of a urinary catheter

Guidelines on Catheterisation Technique

- Royal College of Nurses (RCN, 2008) and
- National Institute for Health and Clinical Excellence (NIHCE, 2003)

**ASEPTIC TECHNIQUE**

Non-Touch procedure
- preparation of the environment and equipment,

Hand Washing
- considered to be most effective at reducing the risk of hospital acquired infection (*DoH, 2001, pg S21-37; Gould et al, 2007, pg 109-115*)

Use of sterile gloves and disposable aprons

Cleaning of the meatal area with sterile agents and use of sterile lubricating gel

Epic’s recommendations on cleaning the urethral meatus using sterile normal saline and using non-antiseptic lubricating gel were, as admitted by the authors, based on expert opinion.  

(Pratt et al, 2006, pg S30).

RCN guidelines (RCN, 2008) do not specify the type of cleansing solution and, the NIHCE guidelines (2003) leave the choice of cleansing solution to the healthcarer and recommend adherence to local guidelines and policies.
In this study, hence, we set out to identify the relevant literature that exists that could serve as evidence that would settle this discrepancy in opinion.

Opinions have varied over time and from region to region, as to:

- Choice of meatal cleansing solution (whether it is an antiseptic or a simple sterile solution)
- How sterile the whole procedure of catheter insertion should be

**Research Question / Topic**

In Patients requiring urinary catheterisation, is sterile catheter insertion more effective than non-sterile insertion at reducing catheter associated urinary tract infections (CAUTI’s)?
3 systematic reviews were identified:


3. Lockwood et al (2004, pg271 – 291) treated with the issue of sterility at insertion very briefly

These reviews mainly focused on catheter related matters other than use of sterility / Antiseptics at catheter insertion

Their search strategy, therefore, could have resulted in studies relevant to the antiseptic issue being missed and left out
Objectives

Evidence from studies dealing with catheter insertion technique

- Sterile / non-sterile and
- More specifically the steps involved e.g. Antiseptic periurethral cleaning, Hand washing and sterile gloves, and Sterile or antiseptic containing lubricating gel
Criteria for Considering Studies for this Review

INCLUDED:

- Male/Female patients undergoing urinary catheterisation performed by health-careers,
- Short/long term indwelling or intermittent catheterisation,
- Setting: Hospital, Rehabilitation Unit or Nursing home.

EXCLUDED:

- Intermittent self-catheterisation,
- Supra-pubic catheterisation,
- Pre-existing Urinary Tract Infection,
- Urological Surgery,
- Patients on Antibiotics

Study Design

INCLUDED:

- Comparative studies: Randomised Controlled Studies, Non-randomised experimental studies and observational studies with control group

EXCLUDED:

- Studies without Control Groups

Outcome

INCLUDED:

- CAUTI confirmed by Significant Bacteriuria or Clinical symptoms or Urethral colony counts

EXCLUDED:

- Any other outcome

Population

INCLUDED:

- Sterile Urethral catheterisation

EXCLUDED:

- Other forms of catheterisation

Intervention

INCLUDED:

- Non-Sterile Urethral Catheterisation

EXCLUDED:

- Other forms of catheterisation

Comparison

INCLUDED:

- Setting: Hospital, Rehabilitation Unit or Nursing home.

EXCLUDED:

- Any other setting

Comparison

INCLUDED:

- Setting: Hospital, Rehabilitation Unit or Nursing home.

EXCLUDED:

- Any other setting

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- Comparative studies: Randomised Controlled Studies, Non-randomised experimental studies and observational studies with control group

EXCLUDED:

- Studies without Control Groups
## Search Strategy

### Comprehensive Electronic and Manual searches

<table>
<thead>
<tr>
<th>Data Bases Searched (Ovid Host)</th>
<th>Dates Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Journals @Ovid Full Text</td>
<td>Up to Sept 02, 2008</td>
</tr>
<tr>
<td>Ovid Medline (R)</td>
<td>1950 to August 2008</td>
</tr>
<tr>
<td>CINAHL</td>
<td>1982 to August 2008</td>
</tr>
<tr>
<td>AMED</td>
<td>1985 to August 2008</td>
</tr>
<tr>
<td>EMBASE</td>
<td>1988 to Week 35, 2008</td>
</tr>
<tr>
<td>EBM Reviews</td>
<td>1991 to August 2008</td>
</tr>
<tr>
<td>BNI</td>
<td>1985 to August 2008</td>
</tr>
</tbody>
</table>
Search Strategy cont...

Manual searches were also performed by:

- Scanning the reference lists of all related studies
- Searching for Grey Literature
- Searching for any possible ongoing Research
Generation of Search Term and Combination List

This process consisted of the following steps;

• The Question was Broken down into the component parts specified by PICO Framework

• Identification of Key words and Phrases and their Synonyms

• Combining of Keywords and Phrases using Boolean operators

• Identifying Abbreviations and different spelling

• Constructing a Search Strategy Table and Translating into a Search Terms and Combination List

The objective was to compile a list of words that authors might have used in their studies, in order to increase sensitivity and specificity of the search.
<table>
<thead>
<tr>
<th>The Search Term Strategy List</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Urethral catheter?ation</td>
</tr>
<tr>
<td>4. Catheter?S</td>
</tr>
<tr>
<td>5. Catheter insertion</td>
</tr>
<tr>
<td>6. 1 or 2 or 3 or 4 or 5</td>
</tr>
<tr>
<td>7. Sterile</td>
</tr>
<tr>
<td>8. Aseptic</td>
</tr>
<tr>
<td>9. Periurethral cleaning</td>
</tr>
<tr>
<td>11. Chlorhexidine</td>
</tr>
<tr>
<td>13. Savlon</td>
</tr>
<tr>
<td>14. Povidone-iodine</td>
</tr>
<tr>
<td>15. Antiseptic solution$</td>
</tr>
<tr>
<td>17. Glove$</td>
</tr>
<tr>
<td>18. Gel</td>
</tr>
<tr>
<td>19. Lubricating gel</td>
</tr>
<tr>
<td>20. Antiseptic gel</td>
</tr>
<tr>
<td>21. Hand washing</td>
</tr>
<tr>
<td>22. Hand Hygiene</td>
</tr>
<tr>
<td>23. 7 or 8 or 9 or 10 or 11 or</td>
</tr>
<tr>
<td>12 or 13 or 14 or 15 or 16 or</td>
</tr>
<tr>
<td>17 or 18 or 19 or 20 or 21 or 22</td>
</tr>
</tbody>
</table>
Results of the search

**THE ELECTRONIC DATABASE SEARCH**

- Total Results: 2687
- Limits were applied: 2628

Irrelevant studies (concerning vascular Catheterisation) eliminated by conducting a further search using urethral, bladder, and urinary as search term combination.

- Hit count reduced to: 1515

- Duplicates removed: 1433

Only 27 of these studies and 4 other relevant studies yielded by Hand searches were included in the first selection process.
Methods of the Review

Three phases:

1. Study Selection process

2. Assessment of the methodological qualities of the selected studies

3. Data extraction process

All three phases were carried out by one of the authors due to restrictions of time and work constraints.
Methods of the Review

1. Study Selection process

<table>
<thead>
<tr>
<th>First Selection of Studies (Based on Title and Abstracts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of Study 1:</td>
</tr>
<tr>
<td>TITLE: Randomised study of sterile versus non-sterile urethral catheterisation.</td>
</tr>
<tr>
<td>(Authors: Carapeti EA, Andrews SM, Bentley PG)</td>
</tr>
<tr>
<td>Reviewer’s name: Fiona Bezzina</td>
</tr>
<tr>
<td>Date: 4 Sept 2008</td>
</tr>
</tbody>
</table>

### First Stage: Title and abstract
- 13 Studies

### Second Stage: Reading the full text
- 8 Studies

<table>
<thead>
<tr>
<th>Second Selection of Studies (Based on Full Text)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of Study 1:</td>
</tr>
<tr>
<td>TITLE: Randomised study of sterile versus non-sterile urethral catheterisation.</td>
</tr>
<tr>
<td>(Authors: Carapeti EA, Andrews SM, Bentley PG)</td>
</tr>
<tr>
<td>Reviewer’s name: Fiona Bezzina</td>
</tr>
<tr>
<td>Date: 4th Sept 2008</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PARTICIPANTS</th>
<th>CRITERIA</th>
<th>YES / NO / UNDECIDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients undergoing catheterisation?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Type of catheterisation: urethral, indwelling or intermittent?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Catheterisation performed by healthcare worker?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Setting: Hospital or Nursing Home?</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>CRITERIA</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile / Aseptic Catheter Insertion, Non-sterile / Clean Catheter Insertion?</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TYPE of STUDY</th>
<th>CRITERIA</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative, Comparative?</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ACTION (with Rationale)</th>
<th>CRITERIA</th>
<th>INCLUDE (read full article) or EXCLUDE?</th>
</tr>
</thead>
<tbody>
<tr>
<td>INCLUDE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Standardised forms used in both stages

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2 Stages:
- 13 Studies
- 8 Studies
# List of Included Studies

<table>
<thead>
<tr>
<th>Study No</th>
<th>CITATION</th>
</tr>
</thead>
</table>
2. Assessment of the methodological qualities of the selected studies

**Assessment Tool:**

Adapted version of critical review form designed by Law et al at the McMaster University

*(Critical Review Form – Quantitative Studies ©Law, M., Stewart, D., Pollock, N., Letts, L. Bosch, J., & Westmorland, M. McMaster University)*

**Reasons:**

1. Applied in analysis of all types of Quantitative study designs
2. Set of very detailed guidelines which makes it easier to use and increases its inter- and intra-rater reliability
## SUMMARY of EVALUATION

Study purpose, Background Literature Review was adequate in all 8 studies. 6 studies were RCT and 2 were Cohort studies.

<table>
<thead>
<tr>
<th>Questions</th>
<th>Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample description</td>
<td>5 studies</td>
</tr>
<tr>
<td>Sampling method</td>
<td>1 study</td>
</tr>
<tr>
<td>Group Similarity</td>
<td>3 studies</td>
</tr>
<tr>
<td>Power analysis</td>
<td>2 studies</td>
</tr>
<tr>
<td>Ethical approval</td>
<td>3 studies</td>
</tr>
<tr>
<td>Outcome measure was reliable and valid in 7 Studies</td>
<td></td>
</tr>
<tr>
<td>Detailed description</td>
<td>7 studies</td>
</tr>
<tr>
<td>Contamination Avoided</td>
<td>6 studies</td>
</tr>
<tr>
<td>Co'intervention Avoided</td>
<td>1 study</td>
</tr>
<tr>
<td>Statistical significance &amp; Drop Outs</td>
<td>8 studies</td>
</tr>
<tr>
<td>Analysis method</td>
<td>7 studies</td>
</tr>
<tr>
<td>Clinical Importance</td>
<td>6 studies</td>
</tr>
<tr>
<td>Appropriate Conclusions in 5 Studies</td>
<td></td>
</tr>
</tbody>
</table>
**Purpose of the study:** to assess the rate of UTI after short-term perioperative catheterisation using sterile versus nonsterile insertion techniques and compare the costs.

**Study Design:** Randomised controlled trial

**POPULATION:**

- **Sample size:** 156 participants (Experimental: 82, Control: 74)

**Criteria of diagnosis (CAUTI or Bacteriuria):** UTI defined as Bacteriuria > $10^5$ with or without clinical symptoms

**INTERVENTION:**

- **Experimental Intervention/s:** Hand washing, non-sterile gloves, tap water meatal washing, KY jelly, Catheter held in plastic sheath.
- **Duration of Intervention/s:**
- **Adverse Effects:** None reported
- **Control Treatment/s:** Hand scrubbing, Gown, Sterile gloves, Sterile pack, No-touch technique, Savlon meatal cleansing, Sterile drapes, Sterile lignocaine gel, insertion with forceps
- **Drop-outs:** None reported

**Setting:** Hospital surgical theatres

**UTI Rate according to Gender:** UTI was present in 11.9% of females and in 8.3% of males ($P > 0.1$)
Study Participants

Study sample Size

<table>
<thead>
<tr>
<th>Study</th>
<th>No of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carapeti</td>
<td>156</td>
</tr>
<tr>
<td>Cheung</td>
<td>20</td>
</tr>
<tr>
<td>Webster</td>
<td>436</td>
</tr>
<tr>
<td>Moore</td>
<td>36</td>
</tr>
<tr>
<td>Pickard</td>
<td>46</td>
</tr>
<tr>
<td>Schiotz</td>
<td>519</td>
</tr>
<tr>
<td>Harrison</td>
<td>28</td>
</tr>
<tr>
<td>Cohen</td>
<td>50</td>
</tr>
</tbody>
</table>

Year:
- Carapeti: 1994
- Cheung: 2008
- Webster: 2001
- Moore: 2006
- Pickard: 1996
- Schiotz: 1995
- Harrison: 1980
- Cohen: 1980
Study Participants

Subjects’ Gender

- Males: 1
- Females: 2
- Mixed: 5
Study Participants

Study Setting

- Theatre
- Nursing Home
- Not Specified
- Hospital

Hospital: 7
Nursing Home: 1
Not Specified: 2
Criteria used to define CAUTI

<table>
<thead>
<tr>
<th>Study</th>
<th>Bacteruria</th>
<th>Bacteriuria &gt;10^5 CFU/ml</th>
<th>Bacteriuria &gt;10^6 CFU/ml</th>
<th>Urethral Bacterial colony</th>
<th>Leukocyte Count ≥10/HPF</th>
<th>Symptoms</th>
<th>Antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Catheterisation Type and Reason

<table>
<thead>
<tr>
<th>STUDY</th>
<th>CATHETERISATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TYPE</td>
</tr>
<tr>
<td></td>
<td>Indwelling</td>
</tr>
<tr>
<td></td>
<td>Intermittent</td>
</tr>
<tr>
<td></td>
<td>(Not self-catheterisation)</td>
</tr>
<tr>
<td></td>
<td>Short Term</td>
</tr>
<tr>
<td></td>
<td>Long Term</td>
</tr>
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<td></td>
</tr>
</tbody>
</table>
Intervention

5 studies investigated an element or a combination of elements of the catheter insertion technique

Carapeti et al, 1994
Cheung et al, 2008
Webster et al, 2001
Moore et al, 2006
Pickard et al, 1996

3 studies examined the effect of antiseptic in the lubricating gel, used in catheter insertion, at reducing CAUTI.

Harrison, L. H. (1980)
Cohen, A. (1985)
Hand washing was investigated in two studies; soap and water / a full surgical scrub. Sterile gowns were worn in the intervention groups.

Aprons (non-sterile) were worn in both the intervention and control groups in the study by Cheung et al (2008) and were worn in only the control group in the study by Pickard et al (1996).

Masks were used in both the intervention and the control in one study only (Cheung, 2008).

Gloves: Two of the studies investigated their use by contrasting sterile gloves in the intervention versus non-sterile gloves in the control group (Carapeti et al 1994; Moore et al, 2006).
Intervention

**Sterile Packs** were used in both intervention and control in two studies and in three studies they were used only in the intervention.

**Sterile drapes:** clearly indicated in only two studies; in one study used in both intervention and control whereas in the other study were only used in the intervention.

**Meatal cleansing agent:**

- **Sterile water** used in both intervention and control in 2 studies
- **Chlorhexidine** was used;
  - in the intervention only, in 3 studies; (in the control, tap water or sterile water was used)
  - in both intervention and control in 2 studies.
**Intervention**

**Non-touch technique** (handling the catheter with forceps or by leaving it partially sheathed in its sterile plastic container) in both interventions and controls was clearly indicated in all the studies except one. (Schiøtz, 1995)

**Lubricating gel:**

- **Sterile, antiseptic-free gel** used in both intervention and control in 3 studies (Cheung et al, 2008; Moore et al, 2006; Pickard et al, 1996).

- **Sterile, antiseptic-free gel** used in the intervention versus **non-sterile, antiseptic-free gel** in the control in 1 study (Carapeti et al, 1994).

- **Sterile gel containing Chlorhexidine** used in the intervention in contrast to no gel in the control in 1 study (Schiøtz, 1995).

- **Povidone-iodine-containing gel** used in the intervention against sterile antiseptic-free gel used in the control in 2 studies. (Cohen, 1985; Harisson, 1980)
Results

The results of 5 of the studies suggest that there is no difference in the incidence of CAUTI when non-sterile or sterile catheterisation techniques are used (Carapeti et al, 1994; Cheung et al, 2008; Webster et al, 2001; Moore et al, 2006, and Pickard et al, 1996).

1 study found that there was no advantage in using antiseptic-containing lubricating gel at catheter insertion (Schiøtz, 1995).

The results of 2 studies supported the hypothesis that antiseptic-containing gel reduces the incidence of urinary contamination (Cohen, 1985; Harrison, 1980).
Implications to Practice

Our Appraisal of these studies has revealed:

• major flaws in their study design and execution
• the quality has been judged to range from poor to moderate.

Therefore great caution is to be exercised on translating the findings of these studies into clinical practice.
Limitations of the Review

Small number of studies identified for inclusion (despite the search for studies being as comprehensive as possible)

Most of the studies have been shown to be of poor to moderate quality and therefore one should be extremely cautious at applying their findings

Selection bias is another probable limitation (all publications which were not in English were excluded from the search)

Single rater was involved in this review project

Publication Bias is another possible limitation
Suggestions for Future Research

1. Study design of RCT with strict adherence to random allocation, including stratification and blinding

2. Multicentre studies; improve recruitment and ensure samples of adequate size (which should be determined by a power analysis)

3. Training of those involved in the study with regards to techniques involved and outcome measures.
4. Consensus on a clear definition of what CAUTI is as an outcome and how to measure it reliably; probably definitions relying on symptoms should be avoided given the subjectiveness involved in their identification.

5. A number of different variables should be studied such as effect of different antiseptics and the effect of gender; however, it is essential that not too many variables are investigated simultaneously.
THANK YOU

QUESTIONS ?
REFERENCES

• The Royal Collage of Nursing (2008) Catheter Care, RCN guidelines for nurses.
• Published by the Royal Collage of Nurses: London [RCN online] www.rcn.org.uk/direct (accessed on 19th June 2008).
REFERENCES cont...

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• Critical Review Form – Quantitative Studies ©Law, M., Stewart, D., Pollock, N., Letts, L. Bosch, J., & Westmorland, M. McMaster University