ILMO. SR(A). PREGOEIRO(A) DA AGÊNCIA DE LICITAÇÕES, CONTRATOS E CONVÊNIOS DE MACEÍO - ALICC

TECNOVIDA COMERCIAL LTDA, sociedade com sede na Rua Pereira Coutinho Filho, 727, bairro de Iputinga, nesta cidade do Recife, Capital do Estado de Pernambuco, inscrita no CNPJ sob o nº 01.884.446/0001-99, por seu representante legal que ao final subscreve, **VEM**, mui respeitosamente, **INTERPOR RECURSO**, notadamente pelo **PEDIDO DE DESCLASSIFICAÇÃO**, do concorrente denominado de **NORD PRODUTOS EM SAÚDE LTDA**, amparado na Lei nº 14.133/2021 à decisão proferida pela DD Comissão Permanente de Licitação relativa ao **PREGÃO ELETRÔNICO Nº 066/2024,** amparado no que consta nas cláusulas previstas no presente edital, uma vez que a citada empresa ofertou seu produto fora do que transcreve o presente edital, não atendendo, portanto a descrição ali contida, conforme especificações estabelecidas no **termo de referência** do edital e seus anexos do presente Edital, notadamente no que transcreve em **seus itens 04 e 05,** tudo mediante seguintes termos e amparada também nos preceitos legais e permissivos, previstos na Lei nº 14.133/21.

RAZÕES DO RECURSO

A recorrente em data de 03/09/2024, teve início à abertura das propostas, participou através do Pregão Eletrônico, objetivando habilitar-se e participar da licitação acima citada.

O Ato convocatório, em seu item 6.7.2. diz que "Será **desclassificada a proposta vencedora que não obedecer às especificações técnicas contidas no Termo de Referência**, fato que não ocorreu para os itens 04 e 05, pois os mesmos estão em desacordo ao estabelecido pelo edital.

O edital discriminou claramente os itens 04 e 05 em questão da seguinte forma**:**

> "*Item 04 - Cateter Urinário **Lubrificado**, **Poliuretano** com Revestimento Hidrofílico, Guia de Inserção* e Ponta Flexível-*Masculino Calibre 10 – Catam 435992.*"

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TECNOVIDA HOSPITALAR

"Item 05 - Cateter Urinário, **Lubrificado**, **Poliuretano** Com Revestimento Hidrofílico, Guia de Inserção e Ponta Flexível-Masculino Calibre 12 – Catam 435993."

Acontece, porém, que a empresa **NORD PRODUTOS EM SAÚDE LTDA,** não apresenta em sua proposta todos os critérios necessários solicitados no edital, senão vejamos;

O produto vencedor GentleCath não é composto por "**Poliuretano**" e sim **POBE**, porém em desacordo com o solicitado, conforme abaixo:

Composition:

Component	Composition
Funnel	Polyvinyl chloride (PVC) with di(2-ethylhexyl)terephthalate (DEHT)
Glue (for funnel assembly)	Loctite AA 3921 (UV glue)
Catheter/ tube	M6906-01 composed of 95% thermoplastomer(TPE), 5% Techsurf 15560
Sachet for sterile water	PET/ Al/peelable PE laminate
Sterile Water	Purified water – USP38-NF33 <1231>. Net weight with sachet:male 12 ± 1g. Female 6± 1g Irradiated
Blue Handling sleeve	Low density polyethylene (LDPE) and linear low density polyethylene (LLDPE) with blue colourant
Paper/ film pouch	Lacquered paper 70 (60g paper coated with 10g lacquer) Film: MLP120, a PP/PA/PE coextruded seven layer film
Sticky dot	Bi-adhesive polymer

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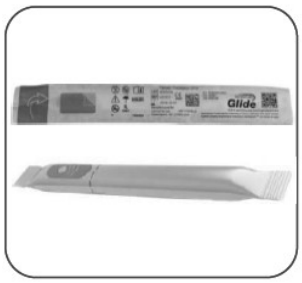
Ficha Técnica

GentleCath™ Glide Cateter Urinário Intermitente Hidrofílico

Cateter Urinário Hidrofílico Masculino



Descrição
GentleCath™ Glide é um Cateter Urinário Hidrofílico, pronto para o uso, estéril, descartável, tubular e flexível, com orifícios polidos e biselados, é inserido através da uretra para a passagem de fluídos da bexiga.

Marca
GentleCath™ ConvaTec®

Composição do Produto
• **Tubo do Cateter**: elastômero a base de poliolefina (POBE) adicionado de aditivos hidrofílicos. • **Conector**: polivinil cloreto (PVC) • **Manga de proteção**: polietileno • **Sachê**: água estéril (esterilização por irradiação beta) • **Material do sachê**: Tereftalato de polietileno (camada externa) / Filme de alumínio / Polietileno (camada interna).

Além do mais a lubrificação do produto vencedor é de 5% TechSurf 15560, polímero responsável pela lubrificação do tubo do cateter e 95% de "THERMOPLASTOMER -TPE" que é um polímero plástico, ou seja, o cateter é apenas 5% lubrificado.

Ressaltamos que a legislação vigente para o uso do cateterismo intermitente, levou em consideração o cateter **SPEEDICATH** como o mais econômico para o sistema de saúde.

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TECNOVIDA HOSPITALAR

PORTARIA Nº 37, DE 24 DE JULHO DE 2019

Torna pública a decisão de incorporar o cateter hidrofílico para cateterismo vesical intermitente em indivíduos com lesão medular e bexiga neurogênica, conforme estabelecido pelo Ministério da Saúde, no âmbito do Sistema Único de Saúde - SUS.

A SECRETÁRIA DE CIÊNCIA, TECNOLOGIA, INOVAÇÃO E INSUMOS ESTRATÉGICOS EM SAÚDE - SUBSTITUTA, DO MINISTÉRIO DA SAÚDE, no uso de suas atribuições legais e com base nos termos dos art. 20 e art. 23 do Decreto 7.646, de 21 de dezembro de 2011, resolve:

Art. 1º Fica incorporado o cateter hidrofílico para cateterismo vesical intermitente em indivíduos com lesão medular e bexiga neurogênica, conforme estabelecido pelo Ministério da Saúde no âmbito do Sistema Único de Saúde - SUS.

Art. 2º Conforme determina o art. 25 do Decreto 7.646/2011, o prazo máximo para efetivar a oferta ao SUS é de cento e oitenta dias.

Art. 3º O relatório de recomendação da Comissão Nacional de Incorporação de Tecnologias no Sistema Único em Saúde (Conitec) sobre essa tecnologia estará disponível no endereço eletrônico: http://conitec.gov.br/.

Art. 4º Esta Portaria entra em vigor na data de sua publicação.

VANIA CRISTINA CANUTO SANTOS

1. RESUMO EXECUTIVO

Tecnologia: cateter com revestimento hidrofílico de poliuretano para cateterismo intermitente (SpeediCath®).

Indicação: pacientes com retenção urinária decorrente de lesão medular.

Demandante: Coloplast do Brasil®

Contexto: No Brasil estima-se que a incidência de trauma raquimedular é de 40 casos novos/ano/milhão de habitantes, sendo que 80% das vítimas são homens e 60% se encontram entre os 10 e 30 anos de idade. As repercussões urológicas causadas pela lesão na medula espinhal constituem um dos principais desafios durante a reabilitação, pois o mau funcionamento vesical pode, quando assistido inadequadamente, acarretar complicações que vão desde a infecção urinária, cálculos vesicais, refluxo vesicoureteral, hidronefrose e, em casos extremos, perda da função renal. No indivíduo com bexiga neurogênica em função da lesão medular deve-se garantir esvaziamento vesical a baixa pressão, evitar estase urinária e perdas involuntárias. Na maior parte dos casos, este esvaziamento deverá ser feito por cateterismo

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3. A TECNOLOGIA

Segundo o parecer submetido pelo demandante, SpeediCath® é um cateter de poliuretano com revestimento hidrofílico pronto para uso e composto por uma camada de lubrificante de alta capacidade de absorção de líquidos. Uma vez que o cateter está exposto a uma solução aquosa, a água é absorvida, resultando em uma superfície suave e homogênea.

A camada lubrificante de polímero hidrofílico é capaz de ligar-se à água e absorver até 10 vezes o seu peso, resultando em uma superfície estável, lisa e escorregadia que assegura baixa fricção entre a superfície do cateter e da mucosa uretral. O revestimento hidrofílico de SpeediCath® é composto por 4 elementos básicos garantindo um revestimento intacto e a lubrificação desejada durante a inserção e retirada do cateter em toda a extensão da mucosa uretral. O tubo principal é constituído por poliuretano ao qual se adere um revestimento base (malha polimérica) e em seguida um revestimento superior altamente hidrofílico, juntamente com um agente umectante.

Vale lembrar que qualquer superioridade em relação a composição deve ser embasada e demonstrada em estudos comparativos.

Dessa forma, o produto não atende aos requisitos solicitados no edital. Todavia o nosso produto SPEEDICATH ofertado para os itens 04 e 05 é o que melhor se adequa e respeita ao descritivo solicitado no edital.

É sabido que as descrições dos produtos no edital são elaboradas de acordo com a necessidade do órgão e que uma divergência de tal magnitude acarretará em diversas objeções por parte dos pacientes que deixaram de ser atendidos conforme suas necessidades.

Por conseguinte, merece a apreciação de V.Sa., desse recurso e por via de consequência, ser **RECONSIDERADA A DECISÃO PROFERIDA**, para ao final ser a empresa **NORD PRODUTOS EM SAÚDE LTDA** seja DESCLASSIFICADA **nos itens 04 e 05** neste processo licitatório, tendo em vista que a mesma não apresentou seu produto em conformidade com o que foi solicitado no presente Edital, por ser de Direito e de Justiça.

Nestes Termos,

Pede deferimento.

Recife (PE), 10 de setembro de 2024

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Marcelo Lopes de Amorim

Coloplast

Ostomy Care
Continence Care
Wound & Skin Care
Interventional Urology

À Quem possa interessar,

Segunda-feira, 15 de março de 2021

Coloplast do Brasil Ltda.
Rua Luis Correia de Melo, 92 - 14º andar, Vl. Cruzeiro, São Paulo-SP CEP 04726-220

CNPJ no.
02.794.555/0001-88

Ref: SpeediCath – Performance e Biocompatibilidade

Prezados(as),

Gostaríamos de oferecer alguns esclarecimentos a respeito da **performance, biocompatibiliade e evidencias clínicas dos produtos pertencentes à família SpeediCath**. Com isso esperamos demonstrar que nosso produto atende a todos requisitos regulatórios aplicáveis.

Esperamos também esclarecer que qualquer comparação com produtos concorrentes que tenha como objetivo indicar superioridade deve ser embasada e demonstrada em estudos comparativos. A simples afirmação de que um produto é superior a outro sem evidencias que suportem a afirmativa pode ser considerada **propaganda enganosa.**

Abaixo, ilustraremos alguns atibutos que foram avaliados durante o desenvolvimento do SpeediCath e através dos quais a comparação deveria ser feita:

- Literatura científica atualmente disponível sobre investigação clínica com dispositivos equivalentes e semelhantes;
- Estudos de performance em cadáveres humanos;
- Dados clínicos relevantes de PMS, incluindo uma avaliação de produto pós-comercialização;
- Testes laboratoriais;
- Resultados somativos de usabilidade;
- Biosegurança.

Como parte do processo de registro sanitário, de acordo com os requisitos da RDC n° 185/2001, relatórios de teste para todos os atributos acima form apresentados a Agencia Nacional de Vigilância Sanitária (ANVISA) para os produtos da família SpeediCath. A seguir focaremos no tema **Avaliação de biocompatibilidade**, a fim de demonstrar nossa completa

adequação aos requisitos apresentaods pela norma **ISO 10993 - Avaliação biológica de produtos para a saúde.**

Critério de Avaliação Biológica	Conclusão
Citotoxicidade de acordo com ISO 10993-5	Nenhuma evidência de citotoxicidade foi observado após a exposição a extratos preparados em meio de crescimento celular no cateter de acordo com ISO-10993-5 (2009). Atende aos requisitos da ISO 10993-5 (2009)
Irritação ou intracutânea Reatividade de acordo com ISO 10993-10	Nenhuma evidência de irritação efeitos foram observados após a injeção intercutânea de extratos preparados em meios polares e não polares. Atende aos requisitos da ISO 10993-10 (2010)
Sensibilização de acordo com ISO 10993-10	Sem evidências de sensibilização da pele foi observada após a exposição da pele a extratos preparados em meios polares e não polares. Atende aos requisitos da ISO 10993-10 (2010)
Toxicidade Subagudo / Subcrônico de acordo com ISO 10993-11	O teste não é considerado relevante. O potencial de induzir toxicidade subaguda / subcrônica sistêmica, toxicidade sistêmica retardada ou toxicidade sistêmica por exposição repetida é contabilizada na avaliação toxicológica. A avaliação toxicológica é baseada em resultados anteriores de testes biológicos dos materiais e dispositivos equivalentes, conhecimento aprofundado sobre as substâncias ingredientes e métodos de fabricação, análise química e caracterização de acordo com ISO 10993-18 (2009), e dados da literatura toxicológica. Esta está de acordo com as recomendações da ISO 10993-11 (2018).
Implantação de acordo com ISO 10993-6	O teste não é considerado relevante para o dispositivo, pois o uso pretendido é intermitente. O cateter será inserido apenas temporariamente na uretra por um curto período (aproximadamente 1 - 5 minutos). Isso está de acordo com a ISO 10993-6 (2007).

Atencisamente,

Daniel da Silva
Gerente de Assuntos Regulatórios e Qualidade

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Letter to Editor

Outcomes comparison of hydrophilic and non-hydrophilic catheters for patients with intermittent catheterization: An updated meta-analysis

Keywords:
Intermittent catheterization
Hydrophilic catheters
Urinary tract infections
Urethral trauma
Cost-effectiveness

To the editor,

At the present, intermittent self- or third-party catheterization is the preferred management for neuro-urological patients who cannot effectively empty their bladders. Hydrophilic catheters (HC) and non-hydrophilic catheters (NHC) are currently the two mainly available catheter types for intermittent catheterization (IC). Despite the tendency to use HC, it remains controversial about the optimal type and technique of catheters and most clinicians still make decisions based on their clinical experience. The latest meta-analysis[1] confirmed the benefits of HC in both urinary tract infection (UTI) and urethral trauma, but they did not consider the effects of age, patient preference, compliance, QoL and cost on the economic sustainability of HC. Thus, we decided to perform an updated meta-analysis of HC versus NHC with regard to UTI, urethral trauma, patient's satisfaction and cost-effectiveness.

We searched PubMed, the Cochrane Library, Embase and Web of Science from the beginning of database to July 2019 with no limitations to language. The inclusion criteria were as follows: (1) randomized control trials (RCTs) comparing HC and NHC for IC with regard to UTIs or urethra trauma or patient's satisfaction; (2) studies that reported cost-effective; (3) the data from included studies could be used directly or could be converted by statistical formula; Exclusion criteria were as follows: (1) non-RCTs and reviews; (2) repeated data; (3) the data from included studies were not in the appropriate format or could not be obtained from the authors; (4) the full text of the study could not be obtained. Studies selection, quality assessment, data extraction and analysis were accomplished by three independent reviewers (DCF, LC and YBY) using Cochrane Collaboration's tools. Disagreements were resolved by another researcher (YJB), and the manuscript was revised by the reviewer (PH). The outcomes of interest were UTI or bacteriuria, urethra trauma (hematuria or bleeding episodes), patient's satisfaction and cost-effective (mean cost, quality-adjusted life years (QALYs), life years gained (LYG), incremental cost-effectiveness ratio (ICER) and Incremental cost-utility ratios (ICUR)). Dichotomous and continuous outcomes were presented as odds ratio (OR) and mean difference (MD), respectively. The fixed effects model was used unless there exists heterogeneity ($p < 0.1$), and significance was set at $p < 0.05$. This meta-analysis was accomplished by RevMan5 (version 5.3).

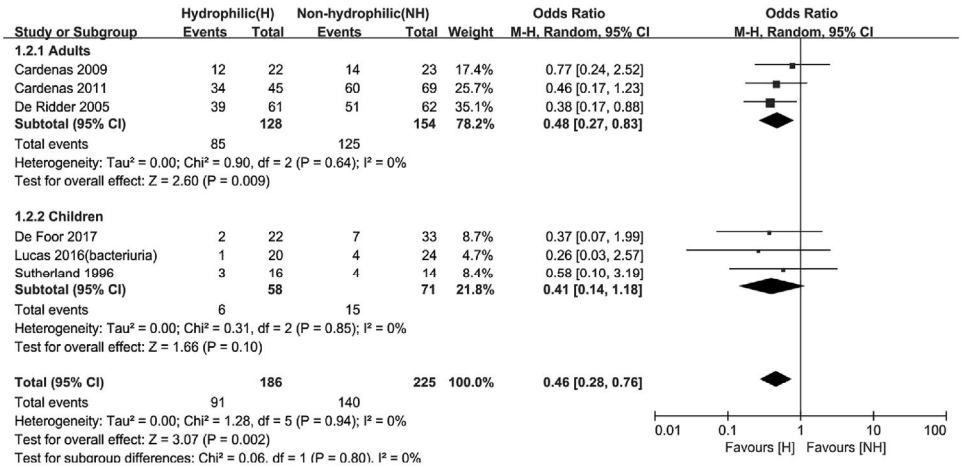
After screening 221 articles, 14 studies (Appendix references 2–15) were included in the final meta-analysis and 8 studies (Appendix references 16–23) were included in the qualitative analysis. We found that the use of hydrophilic catheters (HC), in comparison with NHC, reduced the risk of UTIs by about 54% ($OR = 0.46, p = 0.002$) which was consistent with urethral trauma whose risk reduced by 55% ($OR = 0.45, p = 0.0005$). It is noteworthy that adults are more satisfied with HC ($OR = 1.48, p = 0.04$) while children prefer NHC ($OR = 0.39, p = 0.04$). Fig. 1 sketches these results. Despite the higher unit prices, the additional HC cost was offset from savings due to fewer complications in comparison to NHC when considering over a lifetime from the societal perspective. Besides, the decrease in patient suffering from fewer complications would also add to the benefits of HC. The summary of cost-effective can be seen in Table 1.

This study does have the following limitations. First of all, the broad heterogeneity in study populations, designs and definitions of outcome measures; secondly, reuse of catheters exposes the patient to a plethora of possible cleaning techniques and duration of catheter use; thirdly, we analyzed a trial which enrolled healthy population because our purpose was to compare the effects of these two catheters on urinary tract complications and susceptibility. However, the physical conditions of the healthy population and the patients are different, and thus the resistance to infection is different; last, it is difficult for us to make a definite conclusion due to limited RCTs and sample size.

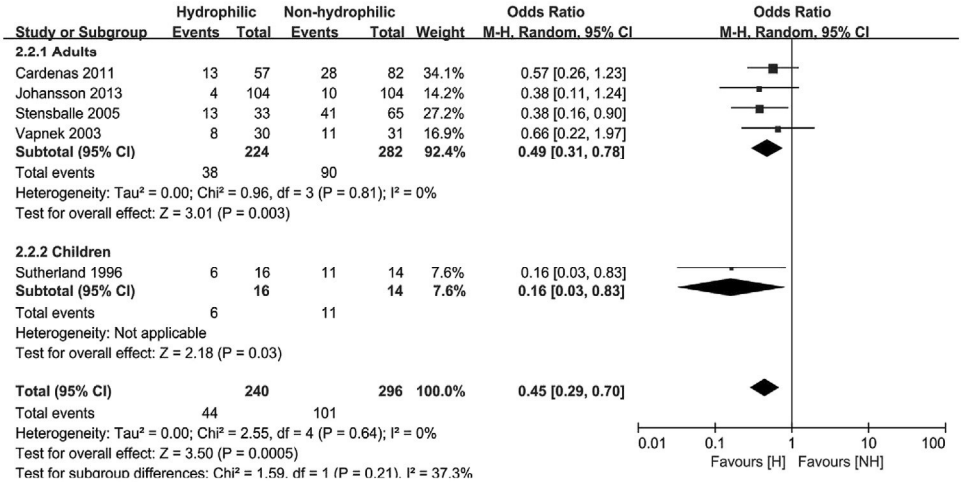
In conclusion, current evidence demonstrated advantages of hydrophilic catheters in decreasing risk of UTIs and urethral trauma as well as improving patients' satisfaction. Further well-designed trials are still needed to confirm these findings and compare the effectiveness and cost-effective of different catheters from the perspective of patients and social willingness.

https://doi.org/10.1016/j.asjsur.2019.12.009

a.Urinary tract infections



b.Urethral trauma



c.Patient's satisfaction

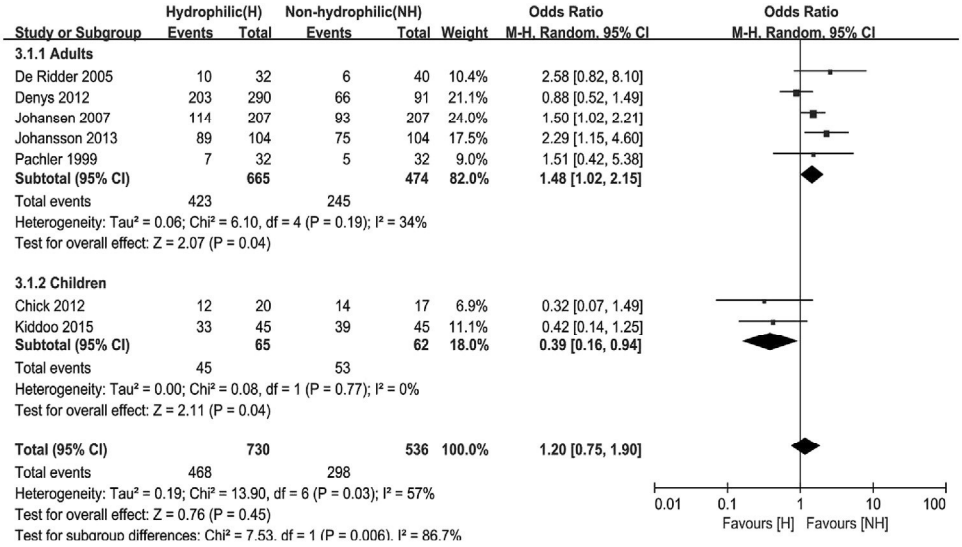


Fig. 1. The pooled results of outcomes.

Table 1
The main characteristics of the included studies related to cost-effective.

Authors	Country or Area	Study Design	Population	Duration	Catheter type (H/NH)	Mean age (H/NH)	Cost-effective (H/NH)
Truzzi 2018	Brazil	CEA/CUA; Markov model	SCI; 80% males	lifetime	H/NH	36	Total QALYs:2.805/2.550 Total LYG:6.233/5.689 UTI events:51.53/54.73 ICER: $32646.58/QALY gained; $15327.0529/LYG; $2609.4847 saved/UTI avoided
Rognoni 2017	Italy	CEA/CUA; Markov mode	SCI; 80% males	lifetime	H/NH (single-use)	40	mean lifetime costs:$93,437/$70,383 Total QALYs:15.170/14.332 Total LYG:18.284/17.299 ICUR: $27382.41/QALY gained; ICER:$23293.842/LYG
Clark 2015	UK	CEA/CUA; Markov mode	chronic urinary retention and a SCI, 80% male	lifetime	H (single-use)/NH (single-use)	36	Total QALYs:6.92/6.58 Total LYG:15.39/14.75 UTI events:143.49/169.98 ICER: $7623.78/QALY gained; $4124.34/LYG; $98.7342/UTI event avoided
Neovius 2015	Sweden	CEA; Markov mode	IC,60% males	NA	H (single-use)/NH (single-use)	NA	Failure:18% vs 35% annual catheter cost:$2272.05/$561 annual complications cost:$1394.646/$2319.174
Bermingham 2013	UK	CEA; Markov mode	neurogenic bladder due to SCI, 80% males, adults	lifetime	H (single-use)/NH (single-use)	40	Total QALYs:12.003/11.780
Håkansson 2016	USA	CEA/CUA; Markov mode	IC,60% males	lifetime	H/NH	40	Total QALYs: 17.18/16.63 complication events:79.82/97.84

NOTE. Values are n, mean + SD, or median (range).
Abbreviations: H:hydrophiliccatheters; NH: non-hydrophilic-coated catheters; USA: United States of America; NA: not available; UK: United Kingdom; CEA: cost-effectiveness analysis; CUA: cost-utility analysis; ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHS, National Health Service; QALY, quality-adjusted life years; ICUR: Incremental cost-utility ratios. IC: Intermittent catheterization.

Ethical approval

The authors have no disclose to ethical statement.

Role of funding source

The study was supported by Pillar Program from Department of Science and Technology of Sichuan Province (2018SZ0219) and the 1.3.5 project for disiplines of excellence, West China Hospital, Sichuan University (ZY2016104).

Declaration of competing interest

The authors have no conflicts of interest.

Acknowledgement

The whole article could be seen in “Appendix Supplementary data”.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.asjsur.2019.12.009.

Reference

1. Rognoni C, Tarricone R. Intermittent catheterisation with hydrophilic and non-hydrophilic urinary catheters: systematic literature review and meta-analyses. *BMC Urol.* 2017;17(1):4.

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2 December 2019
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[1] Dechao Feng and Liang Cheng were contributed equally to this work and should be considered as co-first author.

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UROLOGY - REVIEW

Effects of hydrophilic coated catheters on urethral trauma, microtrauma and adverse events with intermittent catheterization in patients with bladder dysfunction: a systematic review and meta-analysis

Xi Liao[1] · Yuwei Liu[2] · Shiqi Liang[1] · Ka Li[1]

Received: 8 January 2022 / Accepted: 8 March 2022

Abstract

Background Hydrophilic coated catheters are recommended to reduce the side effects of intermittent catheterization (IC) in patients with bladder dysfunction. However, there is lack of Level one evidence to support the use of this intervention.

Search methods Several electronic databases were systematically searched to evaluate complication incidences for hydrophilic coated (HC) and non-hydrophilic catheters (NHC).

Results Twelve studies were eligible for inclusion in the review. The meta-analyses exploring microscopic hematuria frequencies (RR = 0.69; 95% CI 0.52–0.90) and urethral stricture frequencies (RR = 0.28; 95% CI 0.13–0.60) showed a lower risk ratio associated with HC in comparison to NHC, whereas gross hematuria was no statistically significant difference in two groups. Subgroup analyses of gross hematuria which was grouped according to "catheterization frequency", "single/multiple catheterization" and "self/other catheterization" were performed and the values of combined RR were also no statistically significant difference.

Conclusions Compared with non-hydrophilic catheters, the hydrophilic coated catheters have positive significance in reducing the incidence of urethral microtrauma and the urethral stricture. However, more studies are warranted for evaluating effects of hydrophilic coated catheters on the incidence of gross hematuria.

Keywords Hydrophilic catheters · Intermittent catheterization · Hematuria · Urethral stricture · Adverse events

Introduction

Causes of bladder dysfunction are neurogenic or non-neurogenic. Neurogenic bladder dysfunction is often secondary to spinal cord injury and central nervous system disease (multiple sclerosis or spina bifida), of which complications often manifest as urinary tract infections (UTI), urinary incontinence and upper urinary tract lesion [1]. Common non-neurogenic bladder dysfunction includes outlet obstruction, such as benign prostatic hyperplasia and postoperative urinary retention, which probably leads to vesicoureteral reflux. Bladder dysfunction hinders urine discharge, increases pressure in bladder, eventually causes urinary retention, which aggravates the risk of renal failure [2]. The treatment of bladder dysfunction is aimed at alleviating urinary incontinence, protecting the upper urinary tract, and improving bladder function as well as patients' quality of life.

Intermittent catheterization (IC) is a preferred treatment for patients with significant urination problems [3] which is used in 56% spinal cord injury patients for bladder management in the United States [4]. IC makes the bladder store a reasonable amount of urine at low pressure and empty it at appropriate intervals, which simulates physiological urinary function. Thereby, IC prevents overdistention and decreases pressure of bladder [5], improves blood circulation in bladder wall [6], reduces the incidence of urinary retention, and ultimately prevents deterioration of upper urinary tract [7].

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However, there are non-negligible side effects of IC, such as inducible urethral trauma, microtrauma, urethral stricture, bladder stone and false passages formation [8–10]. In recent years, several types of conduits are gradually available for IC to solve these disadvantages, including especially gel pre-lubricated polyvinyl chloride (external lubricant at most) and hydrophilic-coated catheter (polyvinylpyrrolidone coated at most) [10]. Compared with gel pre-lubricated polyvinyl chloride, HC is increasingly used to reduce intubation friction, urethral injury and urethral adhesion due to its special hydrophilic lubrication characteristics and non-sensitization [11].

Three previously published meta-analyses investigated the effects of HC and non-hydrophilic catheters (NHC) on urethral bleeding morbidity in IC patients [3, 12, 13], however, the results were contradictory. In addition, these studies provide few reliable evidence of urethral microtrauma and urethral stricture which are also important outcomes in the early and late stages of IC, respectively, except for gross hematuria. Consequently, the aim of our study is to evaluate whether HC improves the direct adverse effects compared with NHC, especially in urethral trauma, microtrauma, urethral stricture and rare adverse events.

Materials and methods

Inclusion/exclusion criteria

Population Studies considering adults (over 18 years old), adolescents (12–18 years old) and children (less than 12 years old) population with bladder dysfunction requiring IC.

Intervention Hydrophilic catheters—single-use.

Control Non-hydrophilic catheters—single-use or multiple-use.

Outcomes Gross hematuria, urethral microtrauma (microscopic hematuria), urethral stricture, false passages, bladder stone.

Study Randomized controlled trials, controlled before-and-after study, prospective cohort studies and cross-over trials.

Availability English; full text.

Data sources

We searched the following electronic databases to identify studies: Embase, PubMed, The Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Medline, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), British Nursing Index and three Chinese databases (The CNKI, Wan Fang Database and the VIP). The database has been established until December 31, 2021 and the search has been carried out by combining subject words with free words. English search terms include: 1. hydrophilic urethral catheters, hydrophilic-Coated Catheters, hydrophilic coated catheter. 2. Self-lubricated urethral catheters, pre-lubricated catheter, ultra-slippery, aqueous lubrication, surface wettability and lubrication, lubricant, aqueous lubrication, hydrogel coatings hydrogels, aqueous. 3. Reducing friction. 4. Urethra trauma, urethral micro trauma, urinary tract trauma, urethral epithelial micro-trauma. 5. Long-term follow-up study, long-term follow-up, reduce treatment-related complications, adverse events, false passages, urethral stricture, bladder stone. At the same time, the references of the included literatures have been manually retrieved to supplement the relevant literatures.

Literature screening

Two evaluators read the obtained literature independently. After excluding the trials that clearly did not meet the inclusion criteria, the full text of the trials that might meet the inclusion criteria was read to determine whether they really met the inclusion criteria. After the cross-check, if there is a disagreement, a third party will assist in adjudication. Data extraction was performed using standardized forms of the Cochrane Collaboration. The extracted contents include: ① basic information of the included study, ② baseline characteristics included in the study, ③ specific details of the intervention including catheter material/catheter brand, the coating type and the lubrication mode, ④ key factors for the risk of bias include catheter size, self-catheterization or other-catheterization, single-use or multiple-use of catheterization, daily frequency of intubation, ⑤ Outcome indicators and outcome measures.

Bias risk assessment for included studies

Methodologic quality was independently assessed by 2 reviewers using Cochrane.

Statistical analysis

Risk Ratios (RRs) were used as a measure of the relationship between hydrophilic or non-hydrophilic catheters and outcome indicators. The 95% confidence interval (CI) for the dichotomous data was calculated. The pooled RRs were adopted the Mantel–Haenszel method. If there were no events in one or both arms, the Peto method was used. The percentage of variability of each study attributable to heterogeneity beyond chance was evaluated by the chi-square test ($P < 0.10$) and I^2 statistics. According to heterogeneity test, we adopted the random effects model ($I^2 > 50\%$, $P < 0.10$) or the fixed effects model. Then, the

probability of publication bias was evaluated with Egger's test and funnel plots. All statistical analyses were conducted with Stata15.0.

Results

Literature screening process and results

Figure 1 shows the selection process at each step and the reasons for excluded studies. Finally, 12 papers containing 850 participants met the inclusion criteria [14–25], including 9 randomized controlled trials [14, 15, 17, 19, 21–23, 25], 1 controlled before-and-after study [20], 1 prospective cohort studies [18], and 1 cross-over trials [16]. Table 1 illustrated patients' characteristics (age and gender), catheter materials and catheter size. Meta-regression was performed with the year of publication, male proportion and age as independent variables, and the results showed that the regression equation had no statistical significance ($p > 0.05$).

Risk bias assessment form for included studies

In these studies, blinding of participants and interveners were not possible, but even unblinded methods were considered unlikely to have an impact on objective evaluation indicators. Therefore, they were classified as low risk. Patient withdrawal (an average of 17.71%) was common in the literature [14–17, 19, 22–25], which was an unbalanced and potentially biased factors (Fig. 2).

The results of the study

Gross hematuria

Studies have used different terms such as urethral bleeding, hematuria and gross hematuria to describe the same condition. A total of eight trials reported the number of patients with gross hematuria [14–17, 19–22]. The incidence of gross hematuria was 17.9% (57/318) in patients using hydrophilic catheters and 21.0% (73/347) in patients using non-hydrophilic catheters (RR = 0.80; 95% CI 0.45–1.42) (Fig. 3). The risk of gross hematuria was not statistically significant between two groups. As "catheterization frequency", "single/multiple catheterization" and "self/other catheterization" are key indicators for gross hematuria incidence, we performed subgroup analysis for the three aspects. Figure 4 shows that there was still no statistically significant difference in the risk of gross hematuria incidence. In addition, the proportion of male was found that it did not affect the results of the final forest plot of gross hematuria by meta-regression (additional Fig. 3④). Moreover, there was also no evidence of heterogeneity ($p = 0.060$; $I^2 = 55.8\%$) or publication bias ($t = -1.94$, $P = 0.148$) (additional Fig. 3②). For the results of the sensitivity analysis, all the included studies were within the confidence interval except one study at the lower limit of the 95% CI (additional Fig. 3③). In brief, HC did not significantly improve the incidence of gross hematuria compared with NHC.

Microscopic hematuria

In this study, we considered microscopic hematuria as the following definition: the presence of red blood cells (RBC)

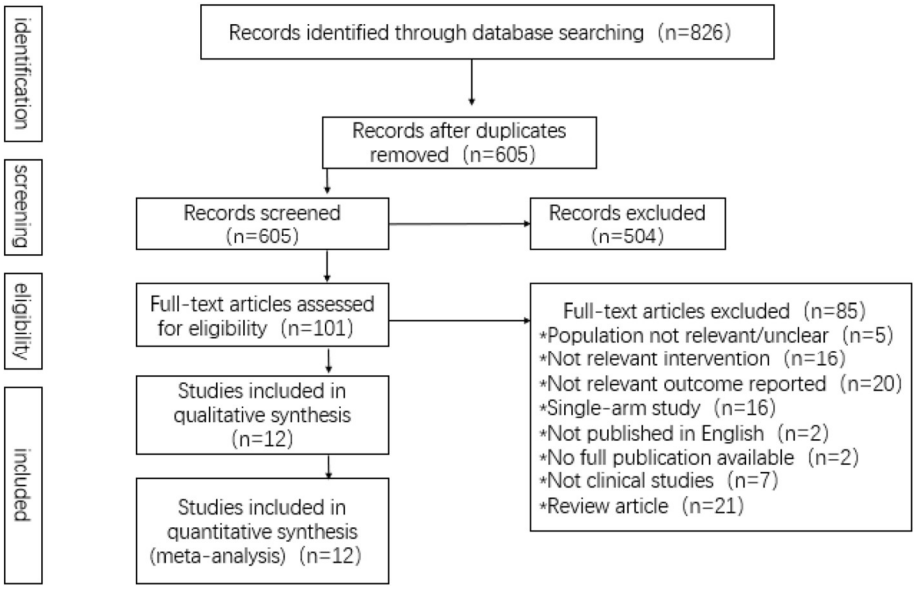

Fig. 1 PRISMA flow diagram—clinical search strategy

Table 1 Summary of extracted clinical data

Study	Location	Age	Gender [a]	Catheter material (brand), C/T[b]	Size
William DeFoor (2017) [14]	America	12.9/13.6	38/40	C: unknown T: unknown/ lofric (Wellspect Healthcare)	Unknown
De Ridder (2005) [15]	Spain, Belgium	37.5±14.6/ 36.7±14.6	M	C:PVC[c] (Conveen,Coloplast) T:PU[d]/Speedicath (Coloplast)	ch10,12,14
Pachler (1999) [16]	Denmark	71.3	M	C:PVC (Mentor santa barbara) T:PVC/lofric (Astra pharmaceuticals)	Unknown
Diana D. Cardenas (2011) [17]	America, Canada	35.1±13.2/ 37.2±14.4	100/39	C:PVC (Conen)T: PU/ Speedicath	Unknown
Tariq Burki (2019) [18]	Saudi Arabia	5	47/54	C:PE[e] T: unknown	Unknown
Ronald (1996)	America	11.7±3.8/ 12.1±5.7	M	C:PVC (Mentor) T:unknown/Lofric	11.5 ± 2.5/11.1 ± 2.1
Wyndaele (2000) [20]	Belgium	45±15	M	C:unknown T:unknown/Urocath-Gel1	12–14 French
Luca Cindolo (2003) [21]	Italy	62.3/67.4	80/20	C:PVC T:PVC/EasiCath (Coloplast, Denmark)	12-Charr
Sataa Sallami (2010) [22]	Tunisia	62/60.9	M	C:PVC T:unknown/LoFric (Astra Tech; Molndal, Sweden)	Unknown/Number 16 or 18
Jonathan et al. (2003) [23]	America	39.8±12.9/ 39.6±16	M	C:PVC T: unknown/Lofric	MOST are 14Fr, a few are 16Fr, 12Fr
Stensballe (2005) [24]	Denmark	24	M	C:silica gel or PVC (incare1 advance plus, Hollister inc,USA) T:unknown/speedicath (Conveen, ColoplastA/S Denmark)	CH12
Kjaergaard (1994) [25]	Denmark	68	M	C:no T: unknown/LoFric	Unknown

[a]Gender: M/ F (male/ female)

[b]T: hydrophilic coated (HC); C: non-hydrophilic catheters (NHC)

[c]PVC: polyvinyl chloride

[d]PU: polyurethane

[e]PE: polyethylene

in high power field under the microscope. There were 3 trials in 12 studies for microscopic hematuria in our study [19, 23, 24]. The incidence of microscopic hematuria was 41.7% (53/127) in patients using hydrophilic catheters and 56.3% (49/87) in patients using non-hydrophilic catheters (RR = 0.69; 95% CI, 0.52–0.90) (Fig. 5). The difference between two groups was statistically significant, indicating that the risk of microscopic hematuria with hydrophilic catheters was only 69% of that in non-hydrophilic group. There was also no evidence of heterogeneity ($p = 0.678$; $I^2 = 0.0\%$) or publication bias ($t = -0.65$, $P = 0.633$) (additional Fig. 5②). For the results of the sensitivity analysis, the included studies were all within the CI (additional Fig. 5③). In short, HC significantly improved the incidence of microscopic hematuria compared with NHC.

Urethral stricture

The method for stricture evaluation is maximum flow rate < 14 mL/s or endoscopic or radiographic examination. A total of five trials reported the number of patients with urethral stricture [14, 15, 21, 22, 25]. The incidence of urethral stricture was 3.1% (6/194) in patients using hydrophilic catheters and 11.5% (23/200) in patients using non-hydrophilic catheters (RR = 0.28; 95% CI 0.13–0.60) (Fig. 6). The difference between two groups was statistically significant,

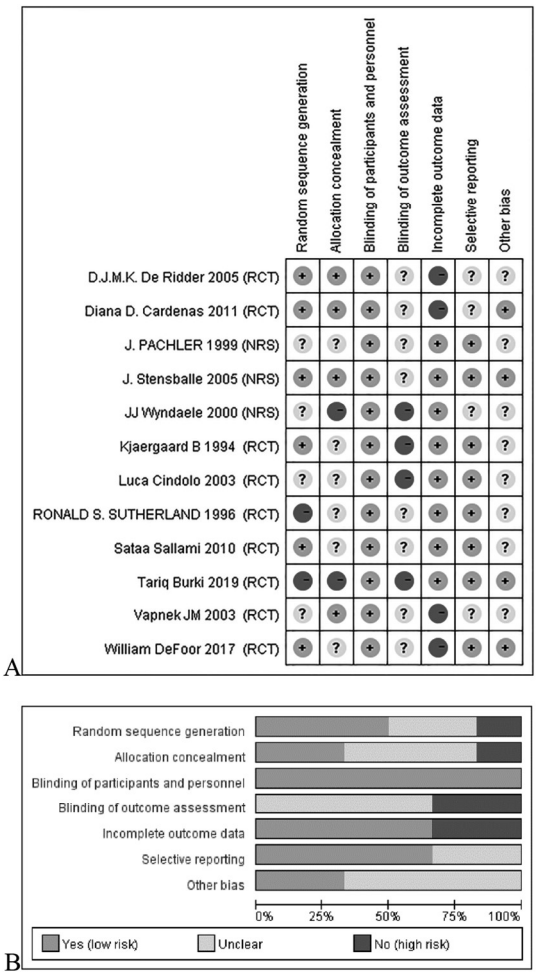

Fig. 2 **A** Risk of bias summary for RCT ($n=9$) and NRS ($n=3$); **B** risk of bias graph for all included studies ($n=12$). *RCT* randomized controlled trials, *NRS* non-randomized controlled trials

suggesting that the risk of urethral stricture with hydrophilic catheters was only 28% of that in the non-hydrophilic group. There was also no evidence of heterogeneity ($P=0.983$; $I^2=0.0\%$) or publication bias ($t=0.69$, $P=0.617$) (additional Fig. 6②). Five studies were all within the 95% CI about the sensitivity analysis (additional Fig. 6③). In a word, HC significantly improved the incidence of urethral stricture compared with NHC.

Rare adverse events

In addition to hematuria and urethral stricture, false passages and bladder stone are also rare adverse reactions after intubation in patients with bladder dysfunction. There were two studies focusing on the incidence of false passages [14, 20] and another two studies on bladder stone morbidity [18, 23]. Wyndaele [20] enrolled 39 patients who had been using NHC for IC over a number of years and switched to urocath-gel hydrophilic lubricated catheter for 1 month. It was found that only NHC group had one false passage. William [14] included children with neurogenic bladder dysfunction and divided them into 41 patients with NHC and 37 patients with HC. There were no false passages patients found in both groups. Jonathan [23] included 30 patients with HC and 31 patients with NHC for neurogenic bladder dysfunction, and found that one patient in each group had bladder stone. Tariq [18] included 101 children with spina bifida and divided them into HC and NHC groups. There were no bladder stones in the two groups. The incidences of both indicators were low after IC, and there was no difference between the two groups.

Discussion

Since Dr. Lapides proposed that using of IC as an alternative way to urinary diversion in《Urology》in 1972 [6], IC has become the globally recognized standard for the treatment of neurogenic bladder dysfunction and has been usually used in managements for various urinary system disease [26]. Generally, IC improves the quality of patients' life through removing long-standing drainage tubes and drainage bags [2]. Initially, catheters for IC were mainly made of latex and rubber. However, these catheters were gradually taken placed by polyvinyl chloride (PVC) catheters due to their sensitization, hardness and difficulty in catheterization [27]. In addition, the practice of re-using catheters with same tube in IC has changed over the past 10 years, for example most patients with intermittent self-catheterization (ISC) were required to use disposable catheters during catheterization [2].

Under the guidance of healthcare workers, almost all patients with bladder dysfunction could get benefits from IC [2]. IC changes the pattern of urinary management in patients with bladder dysfunction because of its various advantages. In addition to decreasing mortality caused by kidney deterioration [28], IC also reduces the harmful effects of long-term indwelling urinary catheters, including urinary tract infections (UTIs) [29], traumatic hypospadias, urinary fistula and even bladder cancer [30]. However, there are still unavoidable complications including mechanical stimulation and mucosa injuries for IC, such as pain and urethral injury. Applying external lubricant is a traditional method to reduce mucosa friction and adhesion during catheterization. Common external lubricants cover Vaseline, paraffin oil, gel, lidocaine cream, amiodarone and ketamine [31]. Nevertheless, the application of external lubricant on the surface of urinary duct has plentiful limitations such as uneven application, cumbersome operation, weak lubrication effect and short residence time. In addition, anesthetic lubricant such as

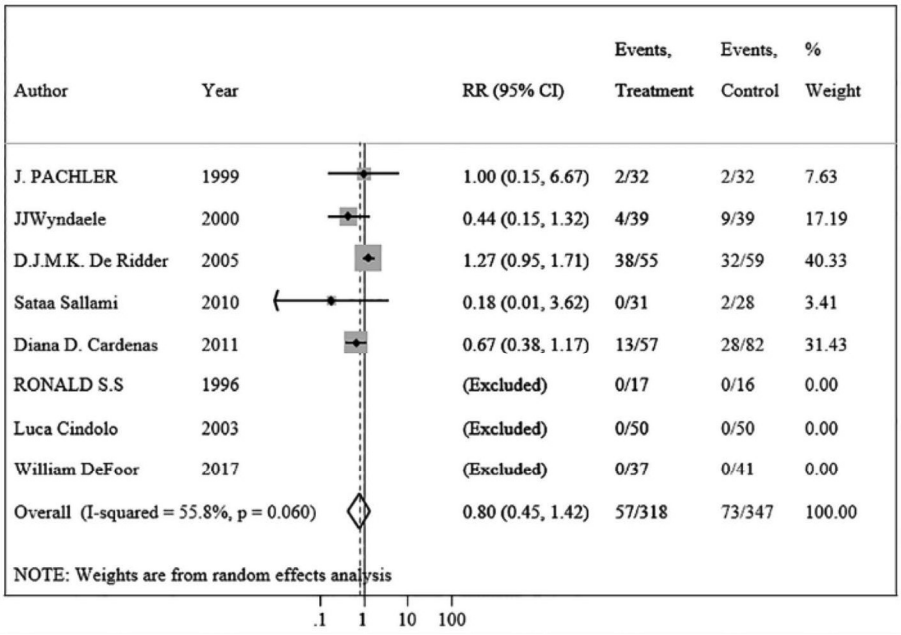

Fig. 3 Meta-analysis comparing hydrophilic catheter with non-hydrophilic catheter, evaluating gross hematuria

lidocaine cream contains additives that cause allergic reactions [32].

In recent years, water lubrication, which is an ideal solution to ultralow friction of medical catheter has received growing attentions. Hydrophilic coated catheters are usually made of PVC material and polyvinylpyrrolidone coated (PVP coated). PVP is a polymer with hydrophilic groups [33]. After the PVP hydrophilic groups are combined with a lubricating fluid (such as water or saline), the interface between the surface of catheter and the urethral mucosa forms a smooth area composed mainly of water molecules [24]. Direct contact between the surfaces is avoided during sliding process, thus greatly reducing friction coefficient and mucosal injury [24, 34, 35]. Furthermore, PVP coated possibly reduce a potential risk of urethral stricture caused by repeatedly intubation [22, 36]. Meanwhile, PVP coated is able to reduce the adsorption of fibrinogen and fibronectin, as well as the deposition of hydroxyapatite on the tube surface [34], potentially resulting in lower incidence of bladder stone.

Generally, gross hematuria is used as an indicator to estimate urethral trauma. However, the results of previous researches were contradictory in regard to whether gross hematuria could be reduced by HC [3, 12, 13]. Two meta-analyses concluded that HC was associated with a reduced risk of urethral bleeding compared with NHC [12, 13], but another research suggested a higher risk of hematuria in the HC group [3]. Simultaneously, the results from the three meta-analyses were challenged due to their inclusion, heterogeneity and bias risk analysis.

Gross hematuria is a more serious outcome indicator, so it is not a favorable indicator for reflecting the early condition of urethral damage. Innovatively, our study assessed urethral microtrauma using microscopic hematuria. Except for urethral bleeding, there are few studies evaluating whether HC reduce the incidence of adverse events, such as urethral stricture, false passages and bladder stone. In our study, HC made positive contributions to reducing the incidence of urethral microtrauma and urethral stricture compared with NHC, whereas gross hematuria was no significant difference. More studies are needed to further confirm the association between HC and these indicators in the future.

Implications for clinical practice

Due to the limitations of the study population and relevant intervention measures, the results of previous studies were contradictory and difficult to be generalized. Our study included a broad population of men and women of all ages with IC. There were no strict restrictions on the influencing factors, including catheterization frequency, self-catheterization or other-catheterization, single-use or multiple-use and the intubation environment. Therefore, our results regarding the complications of HC have broad adaptability to guide clinical practice.

Call for future studies

More high-quality, large-scale RCT studies are urgently needed. Recommendations for future research are as follows: ① The inclusion and exclusion criteria of study subjects should be clarified; ② The specific details of the intervention should be clarified including catheter material/catheter brand, the coating type and the way of lubrication; ③ key

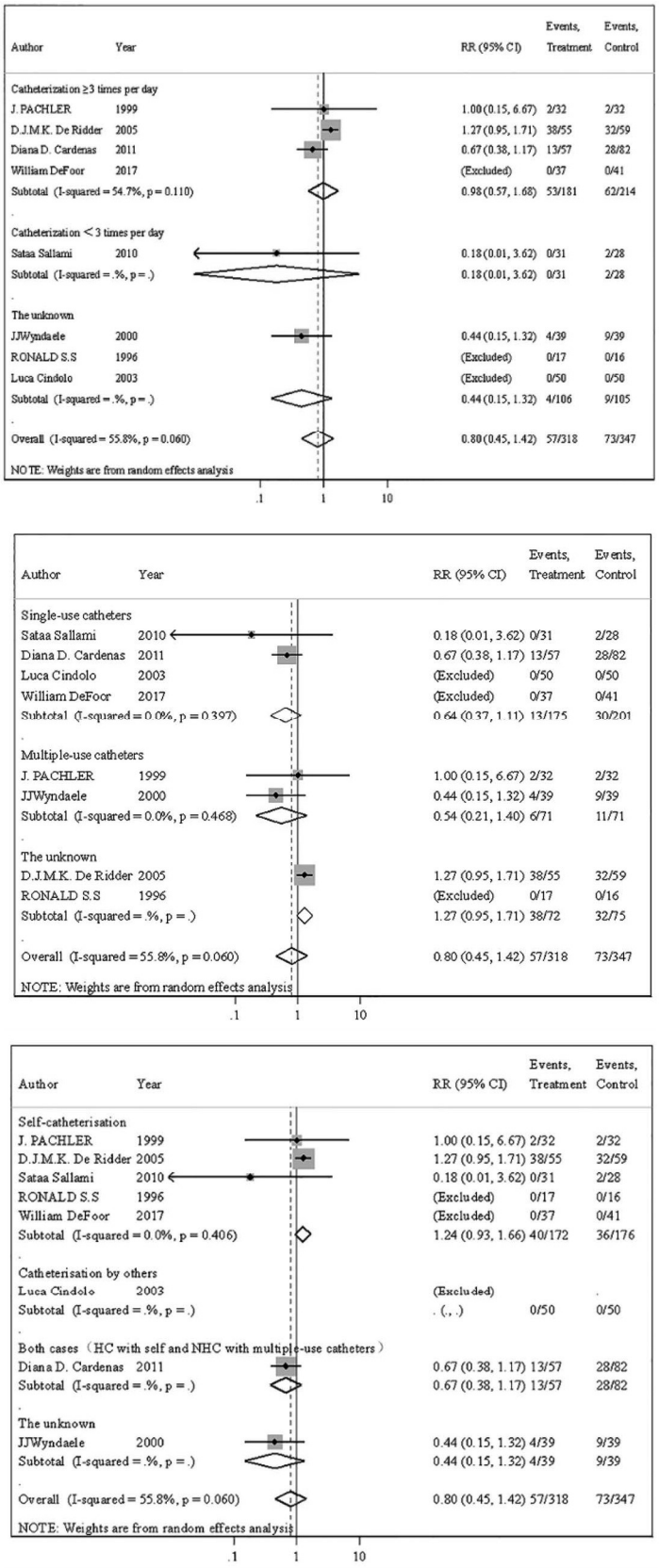

Fig. 4 Meta-analysis comparing hydrophilic catheter with non-hydrophilic catheter, evaluating subgroup analysis of gross hematuria

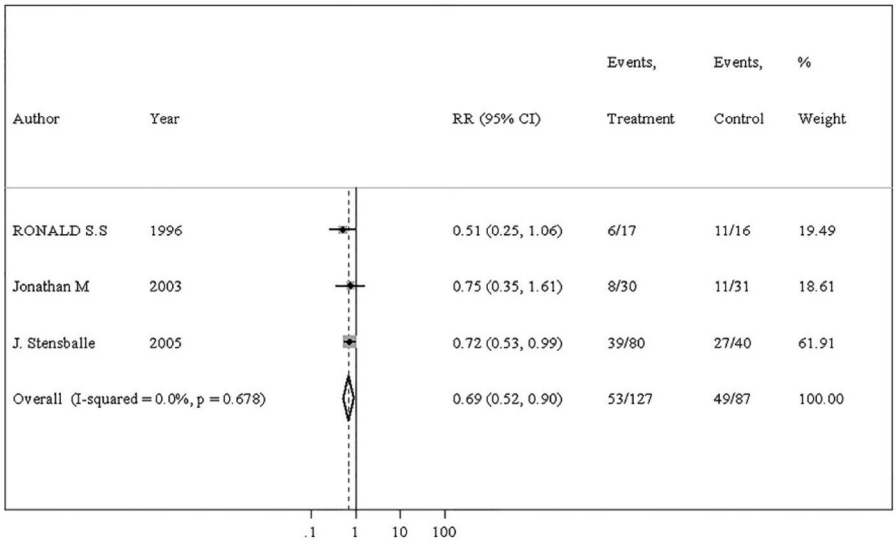

Fig. 5 Meta-analysis comparing hydrophilic catheter with non-hydrophilic catheter, evaluating microscopic hematuria

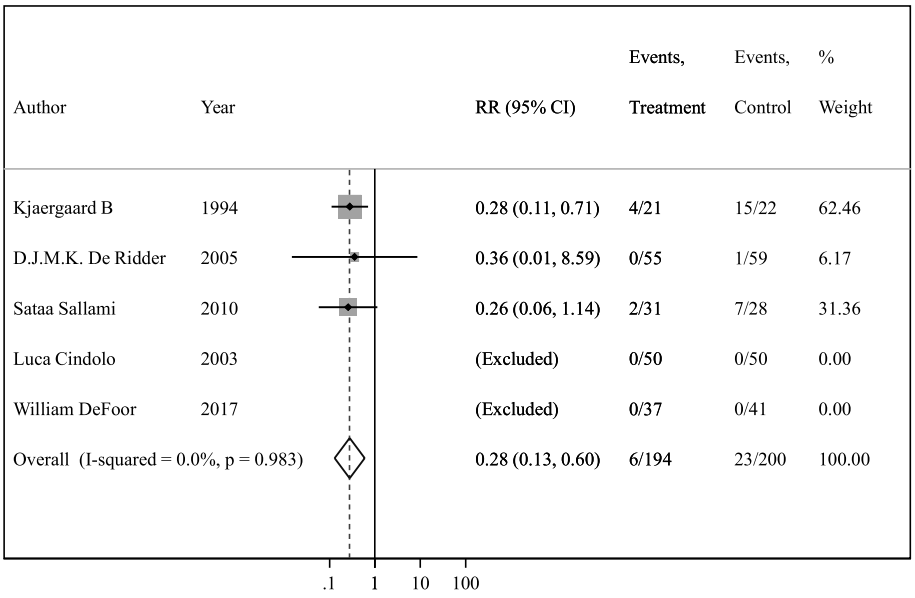

Fig. 6 Meta-analysis comparing hydrophilic catheter with non-hydrophilic catheter, evaluating urethral stricture

factors for the risk of bias need to be controlled including catheter size, total duration of intubation, time to start catheterization, self-catheterization or other catheterization, single-use or multiple-use of catheterization and catheterization frequency; ④ Call for clear definition of outcome indicators and specification of outcome measures.

Limitations

Our study still had some aspects for improving: ① Due to the wide heterogeneity of study subjects, study design, outcome measurement methods, as well as the small number of included literatures, it was difficult to conduct meta-subgroup analysis about long term adverse events such as urethral stricture. Therefore, we only performed subgroup analysis for gross hematuria; ② Risk of bias covers "little blinding of participants and interveners" and "the differences in patient drop-off between the two groups", which perhaps impact study results; ③ The majority of our data was in males and it would be a non-negligible influence factor for IC. However, the objects are only men in the current literature which was eligible for inclusion in these two indicators of microscopic hematuria and urethral stricture.

Conclusion

This meta-analysis supports the benefits of using hydrophilic coated catheters for IC in patients with bladder dysfunction, including reduced incidence of microscopic hematuria and urethral stricture. However, whether HC reduces the risk of gross hematuria has not been proven. While waiting for more evidence, it is recommended to select a more appropriate catheter type of IC combined safety, efficacy, cost effectiveness and patient satisfaction. Patients are advised to use hydrophilic coated catheter as the first treatment option when the condition permits to reduce urethral complications and offers higher comfort [20]. In this study, we evaluated the effects of HC and NHC on urethral trauma, microtrauma, urethral stricture and rare adverse events, demonstrating that HC is a better intubation method for patients with bladder dysfunction.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11255-022-03172-x.

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Declarations

Conflict of interest Xi Liao declares that she has no conflict of interest. Yuwei Liu declares that she has no conflict of interest. Shiqi Liang declares that she has no conflict of interest. Ka Li declares that she has no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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