BEST PRACTICE



Antibiotic prophylaxis in invasive urodynamics, a Delphi consensus of the Italian Society of Urodynamics (SIUD)

Emanuele Rubilotta ¹ 🕟 Elisabetta F. Chiarulli ² Enrico Ammirati ³ 🗅
Marianna C. Bevacqua ⁴ Stefano Manodoro ⁵ 🕞 Stefania Chierchia ³
Eugenia Fragalà ⁶ Giuseppe Masiello ⁷ Vincenzo L. Marzi ⁸ 👨
Alessandro Giammò ² Stefania Musco ⁹ Francesco Savoca ¹⁰
Matteo Balzarro ¹ Cosimo De Nunzio ¹¹ Gaetano De Rienzo ¹² 👨
Ferdinando Fusco ¹³ 📵 Gianfranco Lamberti ¹⁴ 📵 Marco Soligo ¹⁵ 📵
Luisa De Palma ¹⁶ Massimo Fasano ¹⁷ Anna Carretta ¹⁸ Fabio Tumietto ¹⁹
Enrico Finazzi-Agrò ²⁰ 🕟 Eleonora Russo ²¹ Alessandro Antonelli ¹
Marilena Gubbiotti ²² 🕟 Gianluca Sampogna ²³ Michele Spinelli ²³
Roberto Carone ²⁴ Leonardo Martino ²⁵ Vito Mancini ²⁵ Italian Society of
Urodynamics (SIUD)

Correspondence

Vito Mancini, Urology Unit and Renal Transplantation, Policlinico di Foggia, Università di Foggia, Foggia 71122, Italy. Email: mancini.uro@gmail.com

Abstract

Introduction: Although antibiotic prophylaxis (AB) demonstrated a statistically significant reduction in bacteriuria after invasive urodynamics (UDS), no significant decrease in the incidence of urinary tract infections (UTI) has been confirmed. No absolute recommendations on the use of AB in case of relevant potential risk of UTI have been reported, though some categories of patients at increased infective probability after UDS have been recognized. The aim of this study is to report the experts' consensus on the best practice for the use of AB before UDS in the main categories of patients at potential risk of developing UTI.

Materials and Methods: A systematic literature review was performed on AB before UDS in males and females. A panel of experts from the Italian Society of Urodynamics, Continence, Neuro-Urology, and Pelvic Floor (SIUD) assessed the review data and decided by a modified Delphi method on 16 statements proposed and discussed by the panel. The cut-off percentage for the consensus was a \geq 70% of positive responses to the survey. The study was a Delphi consensus with experts' opinions, not a clinical trial involving directly patients.

For affiliations refer to page 6.

Emanuele Rubilotta and Vito Mancini contributed equally to this study.

Results: The panel group was composed of 57 experts in functional urology and UDS, mainly urologists, likewise gynaecologists, physiatrists, infectivologists, pediatric urologists, and nurses. A positive consensus was achieved on 9/16 (56.25%) of the statements, especially on the need for performing AB before UD in patients with neurogenic bladder and immunosuppression. Urine analysis and urine culture before UDS are mandatory, and in the event of their positivity, UDS should be postponed. A consensus was reached on avoiding AB in menopausal status, diabetes, age, gender, bladder outlet obstruction, high postvoid residual, chronic catheterization, previous urological surgery, lack of urological abnormalities, pelvic organ prolapse, and negative urine analysis.

Conclusions: Antibiotic prophylaxis is not recommended for patients without notable risk factors and with a negative urine test due to the potential morbidities that may result from antibiotic administration. However, AB can be used for risk categories such as neurogenic bladder and immunosuppression. The evaluation of urine analysis and urine culture and postponing UDS in cases of positive tests were considered good practices, as well as performing AB in the neurogenic bladder and immunosuppression.

KEYWORDS

antibiotic prophylaxis, Delphi consensus, invasive urodynamics, urinary tract infections

1 | INTRODUCTION

According to leading international scientific societies, antibiotic prophylaxis (AB) is not routinely recommended before invasive urodynamic (UDS) evaluation for patients without risk factors for urinary tract infection (UTI).¹⁻³ However, the main guidelines do not specify which risk factors might make AB beneficial. 1-3 The available data do not record a real advantage in the use of AB, but these few studies have been conducted mostly on female populations without notable risk factors. 4-17 Interestingly, a recent meta-analysis concluded that AB in UDS could decrease the risk of asymptomatic bacteriuria and symptomatic UTI without increasing the rate of adverse events. Usually, the recognized risk factors for developing UTI after UDS are neurogenic bladder, postvoid urine residual (>50 mL), congenital urinary abnormalities, immunosuppression, catheterization, advanced age, recurrent UTI, previous urologic surgery, hypothyroidism, higher pelvic organ prolapse stage, BMI > 30, and bacteriuria. 18 However, most of them are still debated.

Some scientific societies attempted to investigate the major challenge areas in choosing AB before UDS, reporting patient groups at increased risk of complications in cases of AB avoidance with the aim of helping physicians. However, to date, no wide consensus on AB in UDS has been achieved, and it is unclear in which patients' categories ABshould be recommended.

The Italian Society of Urodynamics, Continence, Neuro-Urology, and Pelvic Floor (SIUD) has been involved in the UDS field for over 45 years, also cooperating with other international scientific societies. A panel of SIUD experts has been working on assessing all available data on potential risk factors for UTI after invasive UDS.

The aim of this study is to report the experts' consensus on the best practice for the use of AB before UDS in the main categories of patients at potential risk of developing UTI.

2 | MATERIALS AND METHODS

A systematic literature review was performed in November 2023 using the following keywords: "antibiotic prophylaxis," "bacteriuria," "urinary tract infection," "invasive urodynamic examination," "urodynamic studies," "urodynamics," "pressure-flow studies" for both

nonneurological and neurological patients in PubMed, Cochrane Library, Medline, and Embase according to PRISMA criteria. The search was carried out by two authors (Emanuele Rubilotta and Vito Mancini), and a third author resolved any conflicts in the selection of publications (Matteo Balzarro). The authors manually searched references to primary studies using the same database selection process and furthermore, the relevant journal and bibliographies for additional articles. After duplicate removal (author Emanuele Rubilotta), the remaining papers were assessed. The manuscripts were chosen in the two following steps: (i) title review and structured abstract analysis; and (ii) full-text analysis. The two authors (Emanuele Rubilotta and Vito Mancini) individually completed the collection of articles according to title and abstracts. At each step, each manuscript was reviewed for its appropriateness with regard to the inclusion and exclusion criteria, and its relevance was then graded using the Oxford Centre for Evidence-Based Medicine, Levels of Evidence. In cases of lack of concordance between authors, author (Matteo Balzarro) solved the conflict.

Randomized controlled trials, systematic reviews and meta-analyses, recommendations from the main international scientific societies, and expert opinions were included in the search. Case reports, nonrandomized, and low-quality cohort studies were excluded. Levels of evidence were assigned according to the Oxford Scale. Further recommendations regarding AB in specific patient subgroups were also provided.

Based on this data, the most debated topics in AB before UDS were chosen as statements for the panelists. The panel of experts included urologists, gynecologists, physiatrists, pediatric urologists, infectivologists, and nurses involved in UDS.

A modified Delphi consensus was carried out in a single day. Literature results regarding each statement were shown to the panelist group. Each panelist could assess each statement with a "YES" or "NO," as indicated in the survey. The cut-off to reach the full consensus was a percentage of YES \geq 70%, and all the statements under that percentage were rejected. During debate, the rejected statements with a percentage between 50% and 60% were reassessed by all the experts to identify a possible shared decision.

The following statements have been established based on the current literature:

- 1. Urinalysis and urine culture should be performed on all patients before invasive UDS.
- 2. In patients with positive urinalysis and urine culture, bacteriuria, or symptomatic UTI, invasive UDS should be postponed.

- 3. AB should NOT be administered before invasive UDS in patients with negative urinalysis and urine culture, a normal upper and lower urinary tract, or a lack of any risk factors for UTI development.
- 4. Counseling on AB before invasive UDS should be performed in patients with recurrent UTIs.
- 5. AB should NOT be administered prior invasive UDS based on gender
- 6. AB should be administered before invasive UDS in patients with neurogenic lower urinary tract dysfunction.
- 7. AB should be administered before invasive UDS in patients with high post-void urine residual.
- 8. AB should NOT be administered before invasive UDS in patients with bladder outlet obstruction without high post-void urine residual
- 9. AB should be administered before invasive UDS in patients older than 70 years.
- 10. AB should NOT be administered before invasive UDS in patients with diabetes.
- 11. AB should be administered before invasive UDS in patients with a Body Mass Index $> 30 \text{ kg/m}^2$
- 12. AB should NOT be administered before invasive UDS in patients with menopausal status.
- 13. AB should be administered before invasive UDS in patients with chronic catheterization.
- 14. Counseling on AB before invasive UDS should be performed in patients with previous urologic surgery.
- 15. AB should be administered before invasive UDS in patients with a state of immunosuppression.
- 16. AB should NOT be administered before invasive UDS in patients with pelvic organ prolapse.

We decided not to recommend specific schemes of antibiotic therapies because they can change according to the geographical areas due to different microbial resistances and local stewardship.

3 | RESULTS

A total of 117 articles were selected from the search, and only 17 were included in the analysis of the statements. There were nine reviews, recommendations of guidelines from international scientific societies, expert opinions, and eight randomized trials (RCTs). Of the latter, seven reported that AB did not significantly affect UTI after invasive UDS. The results of these studies have been widely reported in reviews that advise omitting AB before invasive UDS, especially when the urine test or urine culture is negative. However, poor data were described for patients with associated risk factors. In the

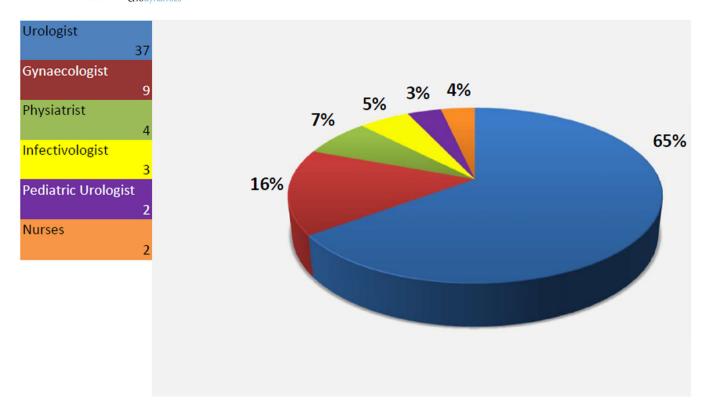


FIGURE 1 Distribution of the panel experts.

TABLE 1 Responses of the experts (yes/no) to the statements; each panelist assessed each statement with yes or no; the cut-off to reach the full consensus was a percentage of yes \geq 70%, and all the statements under that percentage were rejected.

Statement number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Response yes	39	44	50	18	43	40	33	47	17	38	9	46	33	12	53	44
Response no	18	13	7	39	14	17	24	10	40	19	48	11	24	45	4	13
% Yes	70	77.2	87.7	31.6	75.4	70.2	57.9	82.4	29.8	66.6	15.8	80.7	57.9	21	93	77.2

latter, recommendations to AB were mainly based on expert opinion articles and consequently had low levels of evidence in most cases.¹⁹⁻²¹ Neurogenic bladder, postvoid urine residual (PVL > 50 mL), congenital urinary abnormalities, immunosuppression, catheterization, advanced age, recurrent UTI, previous urologic surgery, hypothyroidism, higher pelvic organ prolapse stage, BMI > 30, bacteriuria were reported as the main potential risk factors for UTI after UDS.¹⁸

The panel group was composed of 57 experts in functional urology and UDS, mainly Urologists (Figure 1). The involved experts were 37/57 (65%) urologists, 9/57 (15.8%) gynecologists, 4/57 (7.5%) physiatrists, 2/57 (3.5%) pediatric urologists, 3/57 (5.2%) infectivologists, and 2/57 (3.5%) Nurses (Table 1). A positive consensus was achieved on 9/16 (56.25%) statements.

4 | DISCUSSION

The main data highlight that AB before invasive UDS may reduce the risk of subsequent bacteriuria, but the evidence that this intervention might lower the risk of a consequent UTI is insufficient. Although AB demonstrated a statistically significant reduction in bacteriuria after UDS, no significant decrease in the incidence of UTIs has been confirmed, especially in women. Therefore, there was a general agreement on avoiding AB before invasive UDS in cases of negative urine tests and a lack of both anatomical abnormalities of the urinary tract and high-risk factors. However, no absolute recommendations on the use of ABs in cases of relevant potential risk have been reported, although some categories of patients at increased risk of UTI after UDS have been recognized. 18-21

Our Delphi consensus highlighted the need to perform urinalysis and a urine culture test before UDS, and to postpone the examination in cases of positive analysis. This point is in agreement with the statements of other international societies ¹⁹⁻²¹ to reduce the risks of UTI. Moreover, it is known that UDS results could be misleading in cases of a potential inflammation of the bladder mucosa. There was also consensus on avoiding AB in cases of negative urinalysis and urine culture, normal upper and lower urinary tract, and lack of any risk factor for UTI development to reduce the unnecessary use of antibiotics and the related potential adverse events (statements 1–4).

Gender does not represent a specific risk factor for UTI after invasive UDS.¹²⁻¹³ For this reason, the panel did not recommend administering AB based on the patient's gender (statement 5).

Neurogenic LUTS and neurogenic bladder have been recognized as independent risk factors for UTI development after UDS without AB, with the UTI rate ranging from 7% to 14%, always higher than in non-neurological patients. Therefore, our Delphi consensus recommended the use of AB in this population at increased UTI risk after UDS (statement 6).

Some data reported that greater PVR could represent a potential risk factor for UTI after UDS.¹⁸ However, a standardized threshold for a relevant PVR has not yet been accepted, so it is unclear in which cases the PVR should be considered as high as to require AB. Moreover, the bladder is completely emptied at the beginning and end of UDS by the operator, reducing the risk of infection. Patients with bladder outlet obstruction without elevated PVR have not been considered by the panelists as subjects at higher risk of UTI, due to their bladder emptying, therefore, no consensus on the use of AB has been achieved (statements 7 and 8).

Interestingly, there was a greater consensus in rejecting as risk factors needing AB those conditions with an uncertain role in developing UTI after UDS, such as age, obesity, diabetes, previous urological surgery, and chronic catheterization (statements 9–11, 13, 14). The literature on these topics remains controversial. 19-21

Menopause is not a clear cause of increased urinary infections after UDS, and RCT trials showed no association with an increased risk of UTI after UDS. Hence, our Delphi has decided not to indicate this condition as necessary for an AB (statement 12).

Immunosuppression is a risk factor for any infectious disease, so it is recommended to use AB in these patients before invasive UDS. The majority of experts (93%) agreed that an immune system failure could expose the patient to a higher infectious risk following an invasive

procedure (statement 15). Thus, a large consensus was reached.

Pelvic organ prolapse may be obstructive and may be associated with high PVR. However, with a similar *rational* to that proposed for BOO and high PVR, the Delphi consensus decided to not recommend AB similarly in these patients (statement 16).

Our recommendations partly accord with those of other scientific societies that have reported their views on this topic in the past. 19-21 However, common advice on AB before UDS has been achieved, specifically in cases of neurogenic bladder and immunosuppression. 19-21 Concordance with other international societies was also achieved on the need for urinalysis and urine culture tests before UDS. 19-21 Moreover, there is also an agreement on avoiding AB in cases of normal lower and upper urinary tract and absence of congenital abnormalities, diabetes, menopause, obesity, previous urological surgery, and gender. No accordance with the other scientific societies was shown on the use of AB in cases of older age, higher PVR, chronic catheterization, but these topics are still debated. The rejected statements with a percentage of YES between 50% and 60% (numbers 7, 10, 13) were reassessed by all the experts to identify a possible shared decision. These statements regard high PVR, diabetes, and catheterization and are still debated in the literature. The group of experts decided to reject all those not considered risk conditions for UTI after UDS.

The limitations of our Delphi consensus may be related to the scarce data available in the literature on the role of some potential risk factors for the development of UTI after invasive UDS. The limited data may have reduced the accuracy of the experts' assessment, and in some cases, the decision could be linked only to their expertise. However, this is the common limitation of any Delphi consensus that investigates debated topics.

5 | CONCLUSIONS

AB is not recommended for patients without notable risk factors and with a negative urine test due to the potential morbidities that may result from antibiotic administration. However, AB can be used for risk categories such as neurogenic bladder and immunosuppression. The evaluation of urine analysis and urine culture, postponing UDS in case of their positivity, was considered a good practice.

Our Delphi consensus recommended also avoiding AB before UDS in menopausal status, diabetes, age, gender, BOO, high PVR, chronic catheterization,

previous urological surgery, lack of urological abnormalities, POP, and negative urine analysis.

AUTHOR CONTRIBUTIONS

Emanuele Rubilotta: Conceptualization; data curation; formal analysis: investigation; methodology; supervision; writing—original draft; writing—review and editing. Elisabetta F. Chiarulli: Conceptualization; investigation; writing—review and editing. Enrico Ammirati: Investigation; writing—review and editing. Marianna C. Bevacqua: Investigation; writing—review and editing. Stefano Manodoro: Investigation; writing—review and editing. Stefania Chierchia: Investigation; writingreview and editing. Eugenia Fragalà: Investigation; writing—review and editing. Giuseppe Masiello: Investigation; writing-review and editing. Vincenzo L. Marzi: Investigation; writing—review and editing. Alessandro Giammò: Investigation; writing—review and editing. Stefania Musco: Investigation; writing review and editing. Francesco Savoca: Investigation; writing—review and editing. Matteo Balzarro: Investigation; writing—review and editing. Cosimo De Nunzio: Formal analysis; investigation; methodology; writing review and editing. Gaetano De Rienzo: Investigation; writing—review and editing. Ferdinando Fusco: Investigation; writing—review and editing. Gianfranco Lamberti: Investigation; writing—review and editing. Marco Soligo: Investigation; writing—review and editing. Luisa De Palma: Investigation; writing—review and editing. **Massimo Fasano**: Investigation: writing—review and editing. Anna Carretta: Investigation; writingreview and editing. Fabio Tumietto: Investigation; writing—review and editing. Enrico Finazzi-Agrò: Investigation; writing—review and editing. Eleonora Russo: Investigation; writing—review and editing. Alessandro Antonelli: Investigation; writing—review and editing. Marilena Gubbiotti: Investigation; writing -review and editing. Gianluca Sampogna: Investigation; writing—review and editing. Michele Spinelli: Investigation; writing—review and editing. Roberto Carone: Investigation; writing—review and editing. **Leonardo Martino**: Data curation; investigation; writing—review and editing. Vito Mancini: Conceptualization; data curation; formal analysis; investigation; methodology; supervision; writing—original writing-review and editing.

AFFILIATIONS

¹Department of Urology, Azienda Ospedaliera Universitaria Verona, Verona, Italy

²UO Urologia, ASST-Rhodense (Rho) Milano, Torino, Italy

³Neuro-Urologia, CTO Unità spinale unipolare, Città della Salute e della Scienza, Torino, Italy

⁴UOC Urologia Abilitata al Trapianto, Grande Ospedale Metropolitano di Reggio Calabria, Milano, Italy

⁵UO Ostetricia e Ginecologia Ospedale San Paolo, ASST Santi Paolo e Carlo, Milano, Italy

⁶UO Urologia Ospedale G.B. Morgagni – L. Pierantoni, AUSL Romagna, Forlì, Italy

⁷UO Urologia Ospedale Di Venere, Bari, Italy

⁸Unit of Urological Robotic Surgery and Renal Transplantation, Department of Experimental and Clinical Medicine, Careggi Hospital, University of Florence, Firenze, Italy

⁹Unit of Neuro-Urology, Azienda Ospedaliera Careggi, Firenze, Italy

¹⁰Unit of Urology, Cannizzaro Hospital, Catania, Italy

¹¹Department of Urology, Sapienza University, Ospedale Sant'Andrea, Roma, Italy

¹²Urology and Andrology Unit, Department of Emergency and Organ Transplantation, University of Bari, Bari, Italy

¹³Dep. Urology, Ospedale di Caserta, Caserta, Italy

¹⁴Dep. Rehabilitative Medicine, Azienda USL Piacenza, Piacenza, Italy

¹⁵Unit of Obstetrics and Gynecology, Ospedale Maggiore, Lodi, Italy

¹⁶UOC Medicina Fisica e Riabilitazione, Policlinico di Bari, Italy

¹⁷UO Malattie Infettive, Ospedale Perinei, Altamura, Bari, Italy

¹⁸UOC Malattie Infettive, Policlinico di Foggia, Foggia, Italy

¹⁹UOC Stewardship Antimicrobica, AUSL, Bologna, Italy

²⁰Department of Surgical Sciences, Urology Unit, University of Rome Tor Vergata, Roma, Italy

²¹UO Ginecologia e Ostetricia Universitaria I Azienda Ospedaliera Universitaria Pisana, Pisa, Italy

²²Dep. Urology, Montevarchi, Ospedale La Gruccia, Arezzo, Italy

²³Unipolar Spinal Unit and Neurourology Service, ASST Grande Ospedale Metropolitano Niguarda, Milano, Italy

²⁴Neurourology, Ospedale Koelliker, Torino, Italy

 25 Urology Unit and Renal Transplantation, Policlinico di Foggia, Università di Foggia, Foggia, Italy

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT None declared.

ETHICS STATEMENT

The study was not conducted on patients but on experts' experience.

ORCID

Emanuele Rubilotta http://orcid.org/0000-0002-3490-947X

Enrico Ammirati http://orcid.org/0000-0001-9162-8845

Stefano Manodoro http://orcid.org/0000-0002-1837-0806

Vincenzo L. Marzi https://orcid.org/0000-0002-6328-7980

Stefania Musco http://orcid.org/0000-0001-5844-5684

Gaetano De Rienzo http://orcid.org/0000-00021204-4401

Ferdinando Fusco http://orcid.org/0000-0002-5158-5526

Gianfranco Lamberti http://orcid.org/0000-0002-3288-5275

Marco Soligo http://orcid.org/0000-0003-4586-3195
Enrico Finazzi-Agrò http://orcid.org/0000-0002-0308-8824

Marilena Gubbiotti http://orcid.org/0000-0002-3486-1226

Vito Mancini http://orcid.org/0000-0003-3050-8748

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