Title: Is there outcome reporting heterogeneity in trials which aim to assess the effectiveness of surgical treatments for Stress Urinary Incontinence in women?

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Abstract

Context: Inconsistent outcome reporting of effectiveness outcomes in surgical trials of stress urinary incontinence (SUI) has hindered direct comparisons of various surgical treatments for SUI.

Objective: To systematically review the verbatim outcome names; outcome definitions and tools used to measure the outcomes in surgical trials of SUI in women.

Evidence acquisition: Trials of women with SUI who have undergone surgical interventions were included. We conducted a systematic review (SR) on outcomes reported in RCTs of surgical management published in 2014-2019, covering the following database: MEDLINE, EMBASE, CENTRAL and CDSR. Verbatim outcome names extracted from the included studies were categorized, and then grouped into domains using the Williamson-Clarke (W/C) outcome taxonomy. A matrix was also created to visualize and quantify the dimensions of outcome reporting heterogeneity in SUI trials.

Evidence synthesis: A total of 844 verbatim outcome names was extracted, of which, 514 variated terms were reduced to 71 standardized outcome names. They were further categorized into 11 domains from the W/C taxonomy. There were 7.24 different terms on average to describe each outcome, and the four outcomes with the most heterogeneity evident in terms used to describe them were “Urinary retention”, “Reoperation”, “Subjective cure rate” and “Quality of Life”. Each of them had 20 or more different terms. Only 28% of the outcome definitions were reported, and a variety of measuring tools was noted, particularly in subjective outcomes. High heterogeneity was found in the outcome names; outcome definitions; choice and number of measuring instruments of the outcomes; choice and number of outcomes reported across studies.

Conclusions: This SR provides objective evidence of heterogeneity in outcome reporting in SUI surgical trials. Our categorization of outcomes highlights the difficulties in summarising the current evidence base. A core outcome set, developed using the methods advocated by the COMET and COSMIN initiatives is required.

Patient Summary: In this research we have highlighted the diversity in outcomes reporting in SUI surgical trials, and have categorized the outcomes. We support the development of a core outcomes set for SUI which will promote future clinical researchers to measure the same outcome in the same way in all trials. This will in turn help researchers summarise the evidence more effectively and aid decision making for patients and doctors.

1.Introduction

1.1 Background

Urinary incontinence (UI) is the uncontrolled loss of urine experienced by patients during the phrase of bladder storage [1]. There are three main types of UI: Stress Urinary Incontinence (SUI), Urgency Urinary Incontinence (UUI) and Mixed Urinary Incontinence (MUI). Amongst them, SUI alone accounts for approximately half of all cases of patients with UI [2]. According to the International Continence Society (ICS), SUI is "the involuntary loss of urine on effort or physical exertion, such as sporting activities, sneezing or coughing" [3]. To many SUI patients, the consequences are more than a physical deficit that interferes with their daily activities. Studies have revealed that many women with SUI are stigmatized and isolated due to the condition, which also hampers their sexual and social relationships and results in impairment in their Quality of Life [4,5].

The cause of SUI can be multifactorial but is broadly due to an imbalance or weakness in the mechanical support of the urethra. Intrinsic sphincter deficiency and urethral hypermobility have been postulated as potential causes, with many theories suggested over the years as to how these develop [6]. There is a higher risk of SUI in obese, elderly people, and women who have had vaginal deliveries [7]. In addition, the prevalence of SUI varied greatly across different countries and populations, ranging from 4.8% to 58.4% [2]. The estimated number of people with SUI was 166 million in 2018, with the number of women being almost ten times that of men [8].

Currently, the suggested first-line treatments for SUI are pelvic floor muscle training (PFMT), weight loss and, in some cases, pharmacological agents (such as Duloxetine) [9,10]. Many patients will move on to surgical treatment if they do not respond to first-line treatments. Over the past few decades, there has been an exponential increase in options for surgical treatment of SUI due to technological advances and the development of biocompatible mesh. The number of people receiving surgical treatments has risen through the years, with a 27% increase in the rate of SUI surgery from 2000 to 2009 [11]. Although there is a variation in the techniques being used within each scope, colposuspension, mid-urethral/sub-urethral slings

and periurethral injections of bulking agents are the mainstays of surgical treatment. The mechanism of these procedures is to either partially obstruct the urethra or support the bladder neck [12], thereby reducing the frequency and severity of SUI episodes.

In 1998, the Standardization Committee of the ICS advocated the need to standardize outcome reporting in UI trials [13]. However, there is still a lack of consensus on which outcomes should be reported in UI trials to date. Poor long-term outcome data and inconsistent outcome reporting in SUI trials has been highlighted in most systematic reviews of the effectiveness of the surgical interventions for women with SUI [12,14-19]. The diversity of outcomes reported in SUI RCTs, and heterogeneity in their definitions and measurements has hampered the comparison of the effectiveness of different surgical treatments for SUI and rendered meta-analysis of the data inappropriate [14,17], which eventually resulted in the squandering of limited healthcare resources. Even more, the potential outcome reporting bias may result in a misleading conclusion and end up with the adoption of detrimental treatments in the healthcare sector [20]. Developing a core outcome set (COS) of surgical treatments for SUI may help solve this problem.

The Core Outcome Measures in Effectiveness Trials (COMET) Initiative was launched in 2010, funded by North West Hub for Trials Methodology Research (NWHTMR). Their objectives were to raise awareness of outcome reporting in clinical trials, encourage development of evidence-based Core Outcome Sets (COS) and encourage patients to get involved in this process, save researchers duplication of efforts. According to the COMET Initiative, COS is “an agreed, minimum set of standardized outcome variables which should be measured and reported in all trials for a specific clinical area” [21]. COS aims to mitigate against selective outcome reporting and reduce heterogeneity in outcome definitions and measurement via a systematic, transparent and robust process including key stakeholders such as patients and health care professionals. Therefore, it enables direct comparisons of the effectiveness between treatments and facilitates evidence-based recommendations to decision-makers, clinicians, patients, and other stakeholders. The first step to develop a COS is to systematically review the outcomes reported in the previous trials.

A taxonomy is a scheme of classification developed to overcome the noticeable lack of standardisation of outcome reporting in clinical trials. A standard outcome taxonomy would facilitate literature search by outcome in trial registries. An ideal taxonomy for clinical trial outcomes should be able to comprehensively make clear distinction between high level outcome types (domains) in a sensible hierarchical structure. The taxonomy proposed by Dodd and colleagues known as Williamson/Clarke (W/C) taxonomy is recommended by the COMET. The revised W/C taxonomy consists of 38 items, it was developed to provide a

robust scope to classify COS that are listed in COMET database in a way that classifies what the outcome is at the conceptual level rather than how the outcomes are measured. The W/C taxonomy provides a detailed classification system that comprehensively categorizes all potential outcomes especially those related to domains of physiological/clinical, functioning and resource use, and therefore can be generalized to all clinical trials [23].

1.2 Aim and objectives

This study aims to systematically review the extent of outcome heterogeneity in studies assessing the effectiveness of surgical treatments for SUI in women by summarizing the verbatim outcome names; outcome definitions; and the instruments used to measure the outcomes in trials of surgical treatment of SUI in women.

2. Evidence acquisition

The protocol of this systematic review was registered at the International Prospective Register of Systematic Reviews (PROSPERO Registration number: CRD42019132512). The process of selecting eligible studies and reporting of results followed the COMET Handbook [21] and the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) [22].

2.1 Inclusion criteria

To ensure the most up to date outcomes were identified, studies published in 2014-2019 were included in this systematic review (SR). Only randomized controlled trial (RCT) or quasi-RCT were included in the final analysis, and only publications reported in English were included. Conference abstracts were excluded because they are unlikely to report on all included outcomes or to define them. Adult women aged 18 or above, with SUI or stress-predominant mixed UI, were considered eligible. SUI patients were as classified by the investigators in the included studies. Both newly diagnosed and recurrent patients were included regardless of the severity of the disease. Eligible interventions were any of the nine currently used surgical treatments: Bladder neck needle suspension; Laparoscopic retropubic colposuspension; Open abdominal retropubic colposuspension; Anterior vaginal repair; Periurethral bulking agent injection; Retropubic mid-urethral sling; Traditional suburethral retropubic sling (traditional sling); Single-incision sling; and Transobturator mid-urethral sling [12]. Eligible comparators of trials were any of the nine surgical treatments stated above or placebo as defined by studies. Outcomes of this systematic review were all verbatim outcome names reported in the included studies, the outcome definitions and the instruments used to measure the outcomes.

2.2 Search strategy and eligible studies identification

A two-stage search process was used to identify eligible studies. As a pragmatic decision, the first stage was retrieving studies published in 2014-2017 through the SR authored by Brazzelli and colleagues [12], because it has the same inclusion criteria for the intervention effectiveness part of their project, but conference abstracts, non-English studies and trials including conservative interventions of SUI were excluded in our SR. To ensure we did not miss important outcomes we also searched iteratively one-year back in time, extracted data, then repeated this process for the next year back in time until data saturation. Data saturation was defined as the year in which no new outcomes were identified. In addition, since the last search of Brazzelli et al. SR was in June 2017, our second stage was to perform an updated exhaustive literature search to identify all published RCTs from 1st January 2017 to 15th May 2019. Databases searched included MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL) and Cochrane Database of Systematic Reviews (CDSR) via OvidSP multi-file search. MeSH terms/ EMTREE terms, free text words and word variations were searched for terms related to "stress urinary incontinence AND surgical interventions". Highly sensitive search strategy for identifying RCT, English-language and other exclusion filters were applied to MEDLINE and EMBASE only. Studies including men only, animal studies, studies in children, conference proceedings, case reports, letters and editorials were excluded in the search strategy. Detailed search strategy was reported in Appendix 1. Duplicated studies were eliminated. References of systematic reviews were screened for potential eligible studies. All the abstracts and full texts were screened by one reviewer (FY), and another reviewer (MO/SM) independently screened them again based on the inclusion criteria. Discrepancies were aligned by discussion between reviewers. For the follow-up reports and secondary analysis reports which were published in 2014-2019, the original RCT reports were traced back and included in data extraction and synthesis in order to encompass all the outcomes that have been reported in each trial.

2.3 Data extraction

Data extraction was carried out by one reviewer (FY) with a random 10% data check from a second reviewer (MO). A standardized data extraction form was developed, piloted and used during data extraction. The following data were extracted: verbatim outcome names; outcome definitions reported; instruments used to measure the outcomes; and some basic information about the study (e.g. author name, publication year, length of study, number of participants, countries and types of surgical interventions).

2.4 Data analysis and synthesis

Extracted outcome names were first coded to categorized under common outcome names according to the similarity of concepts and constructs behind to eliminate variations of terms used to describe the same underlying construct. Similar coded outcomes were further grouped in domains by mapping to the W/C taxonomy [23], which is suggested by the COMET Initiative for the classification. Outcome and domain coding were done by one reviewer (FY) and cross-checked by another reviewer (MO). Then, a matrix was created to visualize and quantify the dimensions of outcome reporting heterogeneity in SUI surgical trials. The qualitative information pertaining to the definitions for each outcome were then tabulated and scrutinized to ascertain heterogeneity in the definitions of each outcome and any tools used to measure them.

2.5 Assessment of risk of bias

Assessment of risk of bias was not conducted because there was no estimation of effect sizes of treatments involved. Meta-epidemiological biases identified in the included trials would not affect the results of this SR, nor would help limit the exhaustive list of outcomes required to inform the next (prioritization) stage of the COS and therefore it was deemed an unnecessary waste of resource.

3. Evidence synthesis

3.1 Characteristics of the included studies

Sixty-six eligible reports (including 39 original reports; 17 follow-up reports; and 10 secondary analysis reports of RCTs) [24-89] were identified. In addition, one SR [103] with its latest search on 14th October 2017 was identified. The references list of this SR was checked, and no additional eligible reports were identified. Thirteen additional trials were identified from the studies reporting only the follow-up data or secondary analysis within the search period [90-102]. In total, 79 reports [24-102] coming from 52 trials were included in our SR, for data extraction and synthesis. The flow of literature is graphically illustrated in in the PRISMA flow diagram (Figure 1). Among the 52 identified trials, there are 27 short-term trials (0 to 1 year); 13 intermediate-term trials (more than 1 year, but less than 5 years); and 12 long-term trials (5 years or more).

3.2 Process of categorization of outcome names

To categorize the outcome names (Appendix 2), 844 verbatim outcome names were extracted from the included studies, of which, 330 (39.1%) were duplicates and removed. The remaining

514 outcomes were then organized under 71 common outcome names, which was 13.8% (i.e. 71/514) of the verbatim outcome names. In other words, there were 7.24 different terms on average to describe each standardized outcome and the four outcomes with most different terms used to describe them were “Urinary retention”, “Reoperation”, “Subjective cure rate” and “Quality of Life”. Each of the above-named outcomes had 20 or more different terms. On the other hand, the top five most reported outcomes after coding to our common outcome names were “Subjective cure rate” (44 trials); “Objective cure rate” (42 trials); “Operating time” (41 trials); “Urinary retention” (37 trials); and “Quality of Life” (36 trials). No trials were found to have reported more than half of the common outcomes, and most trials (i.e. 39 trials) have only reported 10-19 of the 71 of the common outcomes.

The outcome names were further grouped into 11 domains based on the W/C taxonomy. [23]: “Mortality/survival”; “General outcomes”; “Renal and urinary outcomes”; “Reproductive system and breast outcomes”; “Physical functioning”; “Global quality of life’; “Perceived health status”; “Delivery of care”; “Hospital”; “Need for further intervention”; and “Adverse events/effects”. The 11 domains have come across all the core areas (Death, Physiological/Clinical, Life impact, Resource use, and Adverse events) as described in the taxonomy. Appendix 2 illustrates the details of the groupings and our categorization of the outcomes under common outcome names and domains.

3.3 Summarizing outcome names and domains by core areas

3.3.1 Death

There was one trial reporting “Death”, which was grouped in the domain: “Mortality/survival”.

3.3.2 Physiological/clinical

The reported outcomes were subsumed in three domains in this core area, including “General outcomes”, “Reproductive system and breast outcomes” and “Renal and urinary outcomes”. Fifteen outcomes (188 verbatim terms, of which 66% were variated outcome terms) were subsumed in these three domains. The outcomes in the “General outcomes” domain were “Perioperative pain score (VAS)” (24 trials), “Duration of postoperative pain” (3 trials), “Estimated blood loss” (24 trials), “Posterior urethro-vesical angles change” (1 trial) and “Length of tape” (1 trial). The outcome in the “Reproductive system and breast outcomes” domain was “Pelvic assessment” (1 trial). The outcomes in the “Renal and urinary outcomes” domain were “Overall continence (objective & subjective cure)” (8 trials), “Objective cure rate”

(42 trials), “Incontinence symptom severity” (13 trials), “Incontinence episodes/day” (9 trials), “Total voids/day” (3 trials), “Bothersome” (3 trials), “Post-void residual” (10 trials), “Parameters of urodynamic tests” (8 trials) and “Duration of catherization” (15 trials).

3.3.3 Impact on quality of Life

The reported outcomes were subsumed under four domains in this core area, including “Physical functioning”, “Global quality of life”, “Perceived health status” and “Delivery of care”. Eleven of our outcomes (146 verbatim outcome names, of which 54.1% were variated outcome terms) were subsumed in these four domains. The outcomes in the “Physical functioning” domain were: “Recovery time” (6 trials), “Functional disability” (2 trials) and “Sexual function” (13 trials). The outcome in the “Global quality of life” domain was the “Quality of life” (36 trials). The outcomes in the “Perceived health status” domain were “Subjective cure rate” (44 trials), “ICIQ score” (4 trials) and “Questionnaire scores” (1 trials). The outcomes in the “Delivery of care” domain were “Patient satisfaction” (18 trials), “Overall experience” (1 trial), “Compliance with study” (2 trials) and “Reasons for non-compliance” (2 trials).

3.3.4 Resource use

The reported outcomes were subsumed in two domains in this core area, including “Hospital” and “Need for further intervention”. Ten outcomes and 150 verbatim outcome names (in which 57.3% were variated outcome terms) were subsumed in these two domains. The standardized outcomes in the “Hospital” domain were “General anesthesia” (11 trials), “Spinal anesthesia” (8 trials), “Local anesthesia” (5 trials), “Combination of anesthesia” (3 trials), “Length of hospital stay” (30 trials), “Operating time” (41 trials) and “Readmissions” (3 trials). The standardized outcomes in the “Need for further intervention” domain were “Reoperation” (25 trials), “Use of analgesics (dose)” (7 trials) and “Pharmacological re-intervention” (4 trials).

3.3.5 Adverse events

The reported outcomes were subsumed in the following domain in this core area: “Adverse events/effects”**.** Thirty-four outcomes and 359 verbatim outcome names (in which 62.1% were variated outcome terms) were subsumed in this domain. The outcomes were “Pain (Abdominal/groin/thigh/vaginal)” (19 trials), “Mesh erosion” (22 trials), “Mesh exposure/protrusion” (21 trials), “Loosened sling” (2 trials), “Anesthesia complications” (1 trial), “Total number of patients with complications” (5 trials), “Embolism” (3 trials), “Blood transfusion” (5 trials), “Severe bleeding” (13 trials), “Post-operative bleeding/hematoma” (20 trials),

“Cardiac adverse events” (1 trial), “Gastrointestinal adverse events” (2 trials), “Urinary tract infection” (22 trials), “Wound infection” (12 trials), “Poor wound healing” (4 trials), “Fever” (4 trials), “Vaginal injury/perforation” (12 trials), “Bladder injury/perforation” (23 trials), “Urethral injury/perforation” (5 trials), “Bowel perforation” (4 trials), “Intraoperative visceral injury” (4 trials), “Skin/musculoskeletal damage” (2 trials), “Neurological damage” (3 trials), “Rectal tenesmus” (1 trial), “Urinary retention” (37 trials), “Duration of intermittent catherization” (1 trial), “De novo urgency” (30 trials), “Overactive bladder symptoms” (10 trials), “Bladder outlet obstruction symptoms” (3 trials), “Incidence of LUTS” (1 trial), “Genitourinary adverse events” (1 trials), “Dyspareunia” (9 trials), “Vaginal bleeding” (3 trials) and “Pelvic organ degradation” (2 trials). The distribution of the adverse events based on different natures of the outcomes as identified in the W/C taxonomy [23] was shown in Figure 2.

3.4 Evaluation of outcome definitions and measuring instruments

Only 236/844 (28%) of outcomes reported were explicitly defined. The definitions and measuring instruments of the two mostly reported standardized outcomes, “Objective cure rate” and “Subjective cure rate”, were analyzed. “Objective cure rate” (Table 1) was defined by 38 trials out of 42. Half of them (21 trials) have defined “Objective cure” solely as “Negative cough stress test”. Three measuring instruments were identified for “Objective cure rate” (Appendix 3). They were the Cough stress test (34 trials), the Urodynamic test (3 trials) and the Pad test (14 trials). Out of the 41 trials which have reported measuring instruments for “Objective cure rate”, there were eight trials using two or more measuring instruments to define the outcome.

“Subjective cure rate" (Table 2), was defined by 38 trials out of 44. Thirteen measuring instruments were identified out of 34 trials, which have reported the measuring instruments (Appendix 3). Ten of them were questionnaires and the three most reported measuring instruments were Patient Global Impression of Improvement questionnaire (PGI-I) (9 trials); International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) (7 trials); and study-specific self-developed questions (7 trials). The most reported definition, though only reported in four trials, was “‘very much improved’ or ‘much improved’ on the PGI-I” [51,60,72,74-75,99,102].

3.5 Comparison with outcomes in 2013 (data saturation to ensure no missing outcomes)

The outcomes we identified were compared against the outcomes reported by studies published in 2013 to ensure no outcome was missed. Fifteen reports were identified that were published in 2013, from the SR by Brazzelli et al. [12]. Six of them were excluded due to ineligible study design, one of them was excluded due to ineligible intervention, and two of them were excluded due to duplication. In total, 66 verbatim outcome names were extracted from the remaining six reports [104-109]. Two additional outcomes: "injury of inferior epigastric vessels" [105] and "injury of the corona mortis" [107] were identified in the search of publications from the previous year. However, both these outcomes were very specific i.e. corona mortis is a variant vascular anastomosis, between the external iliac artery or deep inferior epigastric artery with the obturator artery. Therefore, we took a pragmatic decision to halt any further searches as these two outcomes were too specific. Moreover, in the next phase of our research, involving a patient interview study and a 2-3 round Delphi survey with healthcare professionals and patients, these stakeholders will have the opportunity to raise new outcomes.

3.6 Discussion

From the results, 514 verbatim outcome names were identified. Our data reduction exercise organized these 514 verbatim terms to 71 common outcomes name. This, and the fact that the reporting of these outcomes is sporadic across trials, implies high heterogeneity in evidence base and redundancy in the reported outcome names. Although undesirable, some of this heterogeneity is relatively unproblematic and reflects studies using different terminology to refer to outcomes which essentially relate to the same underlying construct. For instance, studies reported "Urinary retention" as "Urinary retention", "Postoperative clean intermittent catherization", "Elevated postvoid residual", "Voiding difficulties", "Self-catherization" etc. Inconsistent verbatim outcome names were also found within the same report during the data extraction. For example, outcome names could be different in the abstract, main text, and tables reporting the results. In addition, 39 trials (out of 52) have only reported 10-19 standardized outcomes (out of 71), which may indicate selective outcome reporting. This indicates heterogeneity in the choice and number of reported outcomes.

Of concern, many outcomes were not defined, and if they were there is inconsistency in the definitions and measurement tools used to describe the same underlying concept. Only 28% outcome definitions were reported, and there was no one single definition being reported for more than half of the trials for both "Objective cure rate" or "Subjective cure rate" respectively. The same outcome names could be used differently across studies. For example,

“Cured/Failure” could mean “Subjective cure/fail” or “Objective cure/fail” or both in respective studies. Some trials defined “Objective cure” when the patient had “Less than 1 g urine leak in the pad test” [39-41,93], while another defined it as “The pad-weight difference < 2g in pad test” [88]. Some studies even reported the names of questionnaires as their outcome names, which confused the real constructs behind the outcomes. Clearly stated outcome definitions are essential for readers to understand what the outcomes aim to measure.

Some outcomes, particularly patient reported outcomes , were heterogenous in the choice and number of measuring instruments used. For example, among the 13 measuring instruments for “Subjective cure rate”, ten different questionnaires were used across studies. Some studies have even reported more than one questionnaire being used when measuring one specific outcome. This hampers evidence synthesis processes such as meta-analysis and narrative synthesis making critical reviews of the evidence base much more difficult and in turn creates difficulties in the process of making recommendations for clinical practice guidelines and ultimately impedes clinician and patient decision-making.

3.7 Strengths and limitations

In this systematic review, for the first time we have provided concrete evidence of heterogeneity in the outcome reporting in studies assessing the effectiveness of surgical treatments for women with SUI. Moreover, the categorization of outcomes enables a preliminary overview of the outcomes reported in previous trials and paves the way for our next steps in developing a COS to facilitate future research in female SUI.

There were some limitations in this systematic review. First, due to resource constraints, restrictions such as publication year and language were applied to our search, which means there is a possibility some potentially important outcomes could have been missed. However, next steps within the COS process engages key stakeholders including decision-makers, clinicians and patients, and they have opportunities to suggest outcomes which they regard as important yet were not identified in this systematic review therefore it is unlikely we will miss important outcomes through our intended future research processes. Second, despite the best efforts of the authors in understanding and grouping verbatim outcome names, many outcome definitions were not reported (72%) which obscured the construct of the reported outcomes and added uncertainty to the grouping during categorization.

4. Conclusions

In conclusion, we have provided evidence of outcome reporting heterogeneity in studies assessing the effectiveness of surgical treatments for SUI in women. The heterogeneity arose within and across studies, from several sources: variation of verbatim outcome names in the abstracts, main text and result tables within the same report; variation of outcome names between different studies; variation of the choice and number of the instruments used to measure the outcomes; variation or absence of outcome definitions; and variation of the choice and number of standardized outcomes reported in the study. Next, we will use the results of this systematic review, plus the results of patient interviews to identify patient important outcomes that may not be reflected in the clinical literature to date, to inform a Delphi study with key stakeholders in order to prioritize what outcomes are crucial and should be measured in all trials. This COS for SUI will mitigate against selective outcome reporting and definition and measurement heterogeneity and will facilitate future evidence synthesis and decision making for patients, healthcare professionals, healthcare payers and policymakers.

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