Appraisal of national and international uterine fibroid management guidelines: a systematic review

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Abstract

Background

Guidelines standardise high-quality evidence-based management strategies for clinicians. Uterine fibroids are a highly prevalent condition and may exert significant morbidity.

Objectives

The purpose of this study was to appraise national and international uterine fibroid guidelines using the validated AGREE-II instrument.

Selection Strategy

An electronic database search of PubMed and EMBASE from inception to October 2020 for all published English-language uterine fibroid clinical practice guidelines was undertaken.

Data Collection and Analysis

939 abstracts were screened for eligibility by two reviewers independently. Three reviewers used the AGREE-II instrument to assess guideline quality in six domains (scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, and editorial independence). Recommendations were

mapped to allow a narrative synthesis regarding areas of consensus and disagreement.

Main Results

Eight national (AAGL, SOGC 2014, ACOG, ACR, SOGC 2019, CNGOF, ASRM, and SOGC 2015) and one international guideline (RANZOG) were appraised. The highest scoring guideline was RANZOG 2001(score 56.5%). None of the guidelines met the a priori criteria for being high-quality overall (score >= 66%). There were 166 recommendations across guidelines. There were several areas of disagreement and uncertainty.

Conclusions

There is a need for high-quality fibroid guidelines given heterogeneity across individuals and a large range of treatment modalities available. There are also areas of controversy in the management of fibroids (e.g. Ulipristal acetate, power morcellation) which also should be addressed in any guidelines. Future guidelines should be methodologically robust to allow high-quality decision-making regarding fibroid treatments.

Funding

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Keywords

Fibroids, Leiomyomas, Guidelines

63 **Tweetable Abstract**

64 Current national fibroid guidelines have deficiencies in quality, when appraised using

65 the validated AGREE instrument.

Introduction

Uterine fibroids are common with a cumulative incidence of up to 70-80% at the age of 45 (1). Up to 50% of women with fibroids may be symptomatic, with problematic abnormal uterine bleeding, resulting in attendances to primary or secondary care health facilities. Women may also experience dysmenorrhoea, chronic pelvic pain, and pressure symptoms relating to increased abdominal girth relating to significant fibroid tissue mass. Uterine fibroid symptoms exert a significant impact on workplace absenteeism, ability to partake in physical exercise and interpersonal relationships. There is measurable impact, but also unquantified effect on the health-related quality of life since many women with fibroids will remain undiagnosed and/or suffer symptoms in the community without attending for consultation. Direct costs of hospital admissions alone have been quoted at £86 million in the UK (2); in the absence of unmeasured indirect costs, total costs relating to uterine fibroid pathology are likely to be an underestimate. In the US, direct costs have been calculated at ranging between $4 and 10 billion (2). Women with fibroids must have access to high-quality healthcare given the high prevalence of the condition, the potential for significant morbidity, and given that none of these treatments available are without risk or side effects. Surveys targeted at healthcare professionals who manage such women have revealed inconsistencies in the strategies for assessment and management of fibroids (3,4).

Guidelines facilitate standardised and high-quality healthcare according to an up-to-date evidence base. They improve knowledge and should be unbiased, accessible, and aim to provide clarity in controversial subject areas or transparency where there is a lack of an evidence base. Methodologically, there have been issues with general

guideline development from a historical perspective, with poor reporting of stakeholder involvement, evidence synthesis, and strength of recommendations (5). The Appraisal for Guidelines Research and Evaluation (AGREE) Collaboration was developed in 1998 and uses a validated instrument to appraise guideline quality, intending to overcome these issues.

Objectives

The purpose of this study was to appraise the methodological quality of available published national and international uterine fibroid clinical practice guidelines. High-quality guidelines are likely to contribute substantially to the quality of clinical care in benign gynaecology.

Methods

Search Strategy

This study was prospectively registered with the PROSPERO database (Registration number CRD42021222946). This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) methods (**Figure 1**). PubMed and EMBASE databases were searched electronically in October 2020, using the search terms: fibroid*, leiomyoma*, guideline*, guidance, recommendation* (**Table S1 and S2**). Dates were from inception until October 2020 and were restricted to publications in the English language only. References of retrieved included articles were hand-searched for additional guidelines not identified in the initial electronic database search. Additionally, a hand-search of prominent professional gynaecology websites was undertaken to identify additional guidelines not included in the initial database search. The society websites searched included:

- Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZOG)
- American College of Obstetrics and Gynaecology (ACOG)
- Society of Obstetricians and Gynaecologists of Canada (SOGC)
- American Association of Gynaecologic Laparoscopists (AAGL)
- American Society for Reproductive Medicine (ASRM)
- European Society for Gynaecological Endoscopy (ESGE)
- European Society of Human Reproduction and Embryology (ESHRE)
- Royal College of Obstetricians and Gynaecologists (RCOG)

Selection Criteria, Data Collection

The primary outcome of interest was guideline quality, assessed using the Appraisal of Guidelines for Research and Evaluation II (AGREE-II) instrument(6,7). Published national and international guidelines that make evidence-based recommendations on the diagnosis and assessment of uterine fibroids were included. The guidelines must have been published by a recognised authority, and the most recent iteration of the guideline was included. Guidelines considering a single diagnostic or treatment modality were excluded, in addition to consensus statements and local hospital guidelines.

After removal of duplicates, title and abstract screening was performed independently by two reviewers (AA and NJ). Full texts that were potentially eligible for inclusion were screened by two reviewers independently (AA and NJ). Where there were disagreement regarding potential inclusion a consensus was reached after discussion with a third senior reviewer (SQ). Data were extracted in duplicate (AA and NJ) and included: year of publication, publishing authority, country of publication, recommendations, speciality (whether gynaecological or radiological), and publishing journal.

Three reviewers were involved in the independent appraisal of the included guidelines (AA, NJ and SR). All three reviewers completed training in the use of the AGREE-II instrument for the validated appraisal of guidelines (6). This instrument has also undergone reliability testing (7) and has been cited in over 200 publications and translated into over 20 languages (5). It assesses guideline quality as 23 items organised into six domains: scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, and editorial independence. Each reviewer independently provided a raw score per each item and for the guideline

overall using anchored seven-point Likert scale (“1: strongly disagree” and “7: strongly agree”). These scores were then summed for all reviewers and evaluated as a proportion of the available total score. Each score was then transformed into a percentage. In terms of quality: <33% was considered low quality, >66% was considered high quality, and 33-66% was considered a moderate quality in terms of item, domain, or overall guideline scores (8).

Recommendations were further grouped and mapped according to domains (assessment, medical management, surgical management), to provide a summary narrative regarding areas of consensus and disagreement.

Patients were not involved in the study development.

Statistical Analysis

SPSS was used to calculate descriptive statistics (medians and interquartile ranges).

Main Results

Guideline selection

After a database search, 939 titles and abstracts were screened for eligibility after the exclusion of 457 duplicates **(Figure 1).** Seven national (9–15) and one international guideline were identified (16). One additional guideline was identified through hand-search of society websites. (17)

The nine guidelines included were:

- AAGL practice report: practice guidelines for the diagnosis and management of submucous leiomyomas (9)
- American College of Radiology (ACR) Appropriateness Criteria® Radiologic Management of Uterine Leiomyomas(10)
- Therapeutic management of uterine fibroid tumors: Updated French guidelines, French National College of Obstetricians and Gynaecologists (CNGOF) (11)
- The management of uterine leiomyomas, SOGC (12)
- An evidence-based guideline for the management of uterine fibroids Guideline No. 389-Medical Management of Symptomatic Uterine Leiomyomas - An Addendum, SOGC (13)
- The Management of Uterine Fibroids in Women With Otherwise Unexplained Infertility, SOGC (14)
- ACOG practice bulletin. Alternatives to hysterectomy in the management of leiomyomas (15)
- Removal of myomas in asymptomatic patients to improve fertility and/or reduce miscarriage rate: a guideline, ASRM (17)

- An evidence-based guideline for the management of uterine fibroids, RANZOG (16)

Guideline characteristics

The earliest guideline was published in 2001(16) and the most recent, published in 2019 (13) (**Table S4**). Three guidelines represented the most contemporaneous update from previously published guidelines (11,12,15), with one being a supplement to a previously published work (13). Seven guidelines were drafted in North America (9,10,12–14,17); with one published in Europe (11) and one in Australasia (16). All guidelines were published by specialist recognised gynaecology societies, except one published by a radiology committee (10). All guidelines were written from a high-resource setting perspective. Four guidelines made specific recommendations relating to uterine fibroid diagnosis (9,10,14,16). All guidelines made recommendations regarding fibroid treatment. Two guidelines were limited in scope to the discussion of fibroid-related fertility or pregnancy recommendations (14,17). Stakeholder involvement was not clearly described across the guidelines. None of the guidelines explicitly described any involvement of women with fibroids in the guideline development process.

Guideline quality

The median overall AGREE-II score was 53.6% (IQR 48.44- 55.2%). None of the guidelines met the a priori criteria for being high quality overall (score > 66%). The highest scoring guideline was published in 2001 by RANZOG (16) (56.5%), followed by the 2015 SOGC guideline (12) (56.3%) (**Figure 2)**. Across the guidelines, the highest-scoring domain was clarity of presentation (median score 84%, IQR 78-

84%), whereas applicability and editorial independence domains scored poorly (median score 26%, IQR 21-29% and score 29%, IQR 14-43%, respectively) (**Figure 3**). **Table 1** demonstrates the quality across 23 items for all guidelines.

Guideline recommendations

In total there were 166 recommendations and 23 summary statements across all guidelines.

- There were 32 recommendations relating to the clinical assessment of women with fibroids
- 11 recommendations related to the management of women with asymptomatic fibroids
- 42 recommendations related to medical treatment for fibroids
- 53 recommendations related to surgical treatment for fibroids
- 15 recommendations related to radiological or novel ablative treatments

There was consensus across guidelines regarding only three statements:

- Asymptomatic women with fibroids are best managed expectantly
- Gonadotrophin-releasing hormone analogue treatment is effective at improving haematological parameters pre-operatively in women with anaemia
- Hysteroscopic myomectomy should be considered first-line for the management of symptomatic submucosal fibroids

Otherwise, the recommendation content between guidelines was inconsistently reported or varied in their recommendations. Some examples of the areas with a lack of consensus are described below.

Assessment

- The CNGOF guideline is the only guideline to consider and make recommendations regarding imaging surveillance for women with large fibroids (>10cm) in the premenopausal patient (11). The authors of this guideline recommend annual monitoring in women over 40 years of age (11). Otherwise, the other guidelines did not report on this subject.
- Concern regarding potential pregnancy-related complications is not an indication for treatment except where women have had a previous pregnancy-related complication, then myomectomy may be considered in one guideline (12). However, the CNGOF guideline contradicts this latter statement (11).
- The most recent ACOG guideline advises against surgical treatment in the context of asymptomatic women with rapidly-growing fibroids (15). No other guideline makes recommendations on this topic.
- MRI is recommended in four of the guidelines for fibroid mapping (9,11,12,14). However, there is a lack of precise guidance as to when MRI is recommended in preference to, or in addition to, ultrasound, except in the context of characterising fibroids before uterine artery embolisation (10) or for those wishing to avoid the invasiveness of transvaginal ultrasound ((11).
- Pregnant women with fibroids require increased surveillance in one guideline (12) but not in another, unless symptomatic(11).

Medical treatment

- None of the guidelines make recommendations on the use of tranexamic acid for symptomatic relief of bleeding symptoms.

- NSAIDs are recommended in one guideline (11). However, the RANZOG guideline advises against this treatment because of lack of effectiveness(16).
- Danazol is recommended by the SOGC (12) but advised against in others because of adverse effects and short duration of efficacy (11,14,16).

Surgical treatment

- Only one guideline makes recommendations regarding a waiting period before subsequent pregnancy following myomectomy (12). This guideline recommends a minimum period of six months.
- There is no clear consensus regarding optimal size and number for fibroids when considering a laparoscopic approach. Guidelines recommend consideration of a laparotomic approach in association with lower segment or cervical fibroids (12) or fibroids larger than 6cm, (16) or 8cm (11) or 10cm in diameter (12) or fibroid number greater than three (11).
- Only one guideline makes recommendations regarding strategies to reduce blood loss at myomectomy in regards to misoprostol, tourniquet, gelatin-thrombin-matrix, and uterine artery occlusion (12). Vasopressin is discussed in three guidelines, and recommended by two (11,15).
- Anti-adhesion barriers (11,17) are discussed in two guidelines with conflicting recommendations.
- Both the CNGOF and the ASRM recommend that hysteroscopic myomectomy may be undertaken in those considering future fertility with asymptomatic submucosal fibroids (11,17).

A summary of recommendations is provided in **Tables S5 and S6.**

Supporting evidence

8/9 guidelines use methodology that described a systematic database search (**Table S4**), although the extent of the search strategy described varied. Methods of quality assessment varied among guidelines. The number of supporting citations varied from 6 to 204. The number of Cochrane systematic reviews cited per guideline ranged from 0-7. The number of RCTs referenced per guidelines ranged from 0-25. Only 42 (25.3%) of recommendations were developed using good-quality evidence. None of the recommendations in guidelines specific to fertility had good-quality evidence ratings (14,17). 46 (27.7%) of all guideline recommendations were based on an absence of evidence and represented expert opinion or clinical consensus only.

Discussion

Main findings

Professional gynaecological societies support the use of clinical practice guidelines to provide high standards of clinical care. However, no published uterine fibroid practice guideline was assessed as being of high-quality in this study.

Across the guideline development processes described, there was suboptimal transparency regarding the systematic review strategies and group consensus methods used. Instruments to evaluate the evidence quality (GRADE, Canadian Task Force, US Preventative Services Task Force, SIGN, and the National Authority for Health) were inconsistently used and prohibited easy comparison of the strength of recommendations between guidelines. Consideration of the barriers to guideline application and discussion regarding guideline implementation were limited. Demonstration of costing implications were generally poor. Monitoring and audit criteria were scarcely described. There was an insufficient report of funding sources for all included guidelines. Author' disclosure of interest was also not consistently reported across guidelines. While uterine fibroids are a highly prevalent condition that may exert a significant impact on health-related quality of life, there was no explicit involvement of patients with fibroids as stakeholders in the guideline development process in any of the guidelines.

There have been at least two significant areas of controversy in the last 10 years of fibroid research, mandating a need for high-quality appraisal of the literature to inform clinical decision-making. Five of the guidelines were published after the 2014

FDA warning on power morcellation(18). Two guidelines contextually can be considered outside the scope of this topic (radiological management (10), medical management (13)). There were only 2/166 recommendations relating to power morcellation. Other more focused guidance may be accessed in separate publications by the AAGL and ACOG concerning this topic (12). In November 2020, the European Medicines Agency restricted the use of the selective progesterone modulator ulipristal acetate to women who have experienced failed (or are unsuitable for) surgical treatment because of cases of serious liver injury in the context of uterine fibroid treatment (19). There is a need for guidelines to reflect up-to-date evidence. Significantly, 78% of the guidelines scored as being of low-quality in the update procedure item (median score 19%, IQR 14-19%), which is inadequate.

Strengths and limitations

To our knowledge, this is the first published appraisal of national and international uterine fibroid guidelines. The search strategy was comprehensive, and a validated and reliable instrument was utilised.

However, this study has some limitations. The AGREE-II instrument assesses many domains but does not evaluate the content, or the recentness of included guidelines. Additionally, the reviewers were not blinded to the professional society that developed the guidelines. Prior experience of the societies involved may have led to bias in scoring by the reviewers.

Interpretation

There are apparent methodological deficiencies in the quality of available guidelines relating to the diagnosis and management of uterine fibroids, which may consequently affect the clinical utility of these resources.

There was also variation in the scope of guideline content. For instance, one guideline was limited to discussion of submucosal fibroids (9), leading to recommendations regarding hysteroscopic myomectomy and endometrial ablation techniques. Other guidelines discuss uterine fibroids in the context of fertility (14,17) precluding discussion regarding abnormal uterine bleeding symptoms or hysterectomy. As such, there are several disparate recommendations or summary statements that do not allow for comparison across guidelines. A mere three areas of consensus were found. This inconsistency reflects the numerous differing clinical presentation profiles that women with fibroids may exhibit, relating to any combination of bleeding, bulk, pain, or fertility symptoms. There are also a number of separate treatments available that may warrant discussion in their own right in the guidelines but will be limited by guideline scope.

Notably, findings of recommendation disparity and intra-guideline variation were reported in a systematic review appraising endometriosis guidelines, just as in this review. (8) These authors report inconsistent methods of evidence identification and assessment between guidelines as contributing to this dissimilarity. A purpose of the AGREE-II instrument is to minimise such variation by providing a consistent approach leading to rigour of guideline development. Future guideline developers could incorporate an instrument such as the AGREE-II tool in a development or update procedure (20), in the way that PRISMA is incorporated into systematic

review and meta-analysis methodology. Simon et al (20) also recommend conducting pilot tests to ensure guideline feasibility before publication.

Interestingly, a substantial number of recommendations in fibroid guidelines had no underlying evidence to support them. There are methodological issues with a number of published studies in the area of fibroid research. The Agency for Health Research and Quality in the US has evaluated the methodology used in fibroid studies as often being poor- to moderate- in quality, suffering from lack of blinding, and using inconsistent outcomes and measures (21). As in previous endometriosis research(8), a lack of formal pre-determined priorities in fibroid research has led to an inadequate evidence-base with distinct, separate stems of study and unrelated foci that do not allow meaningful comparison between studies. In a separate study, we identified 30 separate primary outcomes (34 outcome measures) and 232 separate secondary outcomes (178 outcome measures) reported in 38 RCTs investigating surgical and radiological treatment for uterine fibroids (data unpublished). This highlights the unhelpful variation in outcome reporting within fibroid research that likely contributes to disparity in guideline recommendations, and hampers progress towards high-quality clinical care in the field of benign gynaecology. There are many research questions that remain unanswered. For example, there remains a lack of evidence regarding long-term treatment outcomes, particularly from a comparative viewpoint. It is still not fully understood how fibroid characteristics, such as size and number, modify clinical outcomes. The optimal peri-operative adjuvant therapy to improve operative outcomes, such as blood loss, has not been determined. The involvement of diverse stakeholder groups using rigourous

methods for consensus (22) will help to prioritise and standardise recommendation content within guidelines, and will help guide future research priorities.

Conclusions

Future guideline development on the subject of uterine fibroids should be methodologically robust and evidence-based, to allow validity regarding recommendations relevant to important research questions. Current guidelines reveal deficiencies that could contribute to substandard clinical care and lead to inconsistencies in fibroid assessment and management between clinicians.

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Contribution of authorship: AA designed the study, screened abstracts, selected texts that were eligible, extracted data, appraised guidelines, provided the statistical analysis, wrote the first draft, and revised the manuscript. NJ screened abstracts, selected texts that were eligible, extracted data, and appraised guidelines. SR appraised guidelines. SQ helped towards gaining consensus in the selection of guidelines for inclusion in cases of disagreement and reviewed and revised the manuscript.

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Figure and Tables Legends

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