PREFERENCE ELICITATION TOOL FOR ABNORMAL UTERINE BLEEDING TREATMENT: A RANDOMIZED CONTROLLED TRIAL

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Conflict of interest: The authors report no conflicts of interest.

Financial support: This study was funded by a grant to the investigators from the Ralph W.

and Grace M. Showalter Research Trust Fund, which had not involvement in the study design,

conduct, interpretation or dissemination.

Clinicaltrials.gov identifier: NCT01721304;

http://www.clinicaltrials.gov/ct2/show/NCT01721304

This is the author's manuscript of the article published in final edited form as:

Hess, L. M., Litwiller, A., Byron, J., Stutsman, J., Kasper, K., & Learman, L. A. (2015). Preference Elicitation Tool for Abnormal Uterine Bleeding Treatment: A Randomized Controlled Trial. The Patient - Patient-Centered Outcomes Research, 8(2), 217–227. http://doi.org/10.1007/s40271-014-0078-8

Acknowledgement: The authors would like to thank Indiana University employees, Ashley Bozell MPH, Jane Cole CMA, Bindu Dukka MPH, Lynn Nall RN, Andrea Priest MPH and Carol Wuestfeld RN, for their dedication to the recruitment and follow up of study participants.

Running Head: RCT of a preference elicitation tool

ABSTRACT

Background: It is estimated that one-third of women will experience abnormal menstrual bleeding. The majority of these cases are not due to cancer or pregnancy complications, and as a result, women are faced with a variety of treatment alternatives, the selection from which is largely dependent on personal preferences for care rather than clinical outcomes.

Objective: This randomized trial was designed to evaluate a preference elicitation tool to promote physician-patient collaborative decision-making for treatment of abnormal uterine bleeding (AUB).

Methods: Adaptive conjoint analysis (ACA) was used to create a preference-elicitation tool in English and in Spanish. Women with AUB were randomly assigned to ACA or usual counseling at the initial clinic visit at four clinics (three in Indianapolis, IN and one in Southern Pines, NC). The ACA tool elicited preferences across eight attributes: treatment efficacy; sexual function; medical care; cost; fertility; frequency of medication use; permanence; and recovery time. T-tests were used to compare differences in the primary outcomes of decision regret and treatment satisfaction at the follow-up visit. The study was designed to have 80% power to detect significant differences between groups for the primary outcomes of regret and satisfaction.

Results: Women were enrolled in the study between September 2009 and March 2012 in four clinics (three in Indiana and one in North Carolina). 183 participants were randomized to ACA and 191 to usual counseling. Overall, mean (SD) treatment satisfaction was high at 35.71 (9.72) (scale of 0-44), and decision regret was low at 25.9 (21.0) (scale of 0-100), creating ceiling effects for the selected outcome variables; there were no significant differences between the ACA and control group at the follow up assessment. There was a strong inverse relationship

between age and decision regret (p=0.007). Exploratory subgroup analysis in the youngest quartile comprising 64 women age 19-35 showed a statistically non-significant difference in mean regret scores for the ACA group versus usual counseling (24.6 vs. 34.6, respectively, p = 0.08).

Conclusions: A preference-elicitation tool at the initial consultation visit did not reduce decision regret or improve treatment satisfaction among patients with AUB; however, there is a need for additional research to further understand this tool's potential role in promoting collaborative decision making, which may be particularly important among younger women.

Author contributions:

The authors each contributed to and approved the final manuscript for publication. The principal and co-investigators, Drs. Hess, Litwiller, Byron, Stutsman, Kasper and Learman, were responsible for all aspects of the study, including obtaining funding, study design and procedures patient enrollment, and writing the manuscript. Dr. Hess was the primary investigator responsible for grant writing to obtain support for the study, data analysis, Institutional Review Board (IRB) and regulatory responsibilities and led the work on the manuscript. All investigators were responsible for patient recruitment, enrollment, data collection, conduct of study visits, interpretation of data, and revisions and substantial contributions to the manuscript. Dr. Hess is guarantor of the study and accepts full responsibility for the content of this work.

Key points for decision makers

- Individuals seeking care are empowered and expected to engage as active participants; however, there is no standard approach to elicit a patient's preference for treatment alternatives.
- Adaptive conjoint analysis is becoming more common in decision analyses, but has not often been used as a tool to facilitate shared decision making.
- This randomized trial found that using ACA was well accepted and was easily implemented into routine clinical practice but did not demonstrate impact on future treatment satisfaction or decision regret.
- Future studies should assess the impact of adaptive conjoint analysis as a preference elicitation tool on more proximal outcomes.

INTRODUCTION

It is estimated that approximately 30% of women will experience heavy menstrual bleeding.(1) Abnormal uterine bleeding (AUB) is defined as "bleeding from the uterine corpus that is abnormal in duration, volume, and/or frequency" and may be acute or chronic (6 months duration or more).(2) Up to one-third of all outpatient gynecology clinic visits are due to some form of abnormal uterine bleeding (AUB).(3) While this condition is not associated with serious adverse events or mortality, the impact of this condition can be considerable on the patient and others, impacting interpersonal relationships, the ability to engage in social and work activities, and health-care related costs and quality of life.(4, 5) The etiology of AUB is varied and classification systems have been developed to understand the causes of abnormal bleeding in the nongravid woman (6). AUB treatment alternatives include hormonal therapy (i.e. oral contraceptives, progestins, other hormonal treatments), the use of an internal uterine device (IUDs), or the slightly more invasive procedure of endometrial ablation (for those who no longer desire fertility), or inpatient surgical procedures such as hysterectomy. (A table summarizing the most common treatment options is provided as Electronic Supplementary Material.) These therapeutic options are effective across a range of underlying etiologies including ovarian and endometrial dysfunction, small leiomyomata and polyps, and initial treatment for bleeding associated with inherited coagulopathy. In some cases, such as large polyps or cancerous masses, the patient may require surgical intervention. However, for the majority of cases, no clear single option is clinically preferred despite the heterogeneity of the condition (e.g. abnormal ovulation patterns or a disorder of the endometrium both are treated in a similar manner). Therefore, the choice between treatment options is often tailored to patient preference for surgical versus medical management, individual desire to maintain fertility, the

risks and benefits, as well as the costs and time associated with the various treatment options. As a result, the patient consult can be time consuming to enable informed shared patientprovider decision making for the preferred treatment for the patient's AUB.

Patient-centered models of care are becoming the norm, whereby individuals seeking care are empowered to engage as active participants in their care, and to receive treatments and services that reflect their own preferences, desires and needs. However, there is no standard approach to elicit a patient's preference for treatment alternatives. In the setting of AUB, ensuring patientcentered decision making can be difficult given the number of options for care and numerous trade-offs that a patient must make in the selection of treatment. If the physician could elicit patient preferences for the key attributes of treatment alternatives, this could result in efficient patient counseling and subsequent care that is more concordant with patient needs and preferences, which is the ultimate goal of shared decision-making.

This study was designed to develop and test the use of adaptive conjoint analysis (ACA)(4-9) to elicit those individual patient preferences as part of routine clinical care for women diagnosed with AUB. ACA is able to elicit such a summary of patient preferences across a variety of attributes for a wide range of treatment options. ACA works in several phases. First, it asks respondents to rank their preferences across the list of attributes of available treatment options. Then, respondents are sequentially presented with the 'best' and 'worst' scenarios (based on their responses to the ranking exercise) of those attributes, where they are able to rate the choices on an interval scale for levels of importance. Then, attributes are paired and respondents must make choices on a 9-point scale which quantifies how much more one option is preferred to another. Lastly, the participant is presented a series of treatment options combining specific attributes according to her individual preferences, and through an iterative and adaptive process, determines the optimal set of attributes for treatment.(7) As patient-centered care has grown in importance in clinical centers across the U.S., ACA has been used to assist patients and their providers choose among treatment alternatives in a variety of disease settings, such as osteoporosis treatment;(8) knee pain treatment;(9) surgery for colorectal cancer liver metastases;(10) preoperative radiotherapy in rectal cancer;(11) and the choice of care for primary prophylaxis of variceal hemorrhage.(12)

In this study of women with AUB, it was hypothesized that the elicitation and sharing of patient preferences between patient and provider would be associated with greater satisfaction with care and with less decision regret than for patients did not complete the ACA exercise.

MATERIALS AND METHODS

Sawtooth Software SSI Web 6.4.4 was used to develop an ACA survey in English and in Spanish to be administered at the time of the patient's initial clinic visit. The treatment attributes were developed based on the attributes of treatment options available for AUB (i.e., ablation, hysterectomy, IUD, oral hormone medications). Levels of each attribute were also identified based on clinical characteristics of treatment alternatives. The attribute descriptions were presented in a study of eight women who met the eligibility criteria for the randomized study. These participants completed the draft survey and provided qualitative feedback on its presentation, treatment attributes, and the wording of each attribute and levels of each attribute (13). The ACA survey was iteratively revised and finalized based on the results of this pilot testing study. The final ACA survey included eight attributes of the various treatment alternatives that could be possible choices for all eligible participants. These attributes included: treatment efficacy; sexual function; medical versus surgical care; cost; fertility; frequency of medication use; permanence; and recovery time. The study attributes and levels are provided in Table 1. The ACA survey was designed so the irrelevant combinations of attribute levels were excluded from the survey (e.g. a treatment choice with daily pills and hospital stay would not be clinically possible and could not be paired). All study methods and procedures for the pilot testing and the randomized trial were approved by the Indiana University Institutional Review Board prior to initiation of any study activities.

Between September 2009 and March 2012, patients presenting to participating gynecology clinics (Southern Pines Women's Health Center, Southern Pines NC; Primary Care Clinic of Wishard Hospital, Cottage Corner Clinic, or Coleman Center for Women, Indianapolis IN) were enrolled to the study prior to meeting with the physician. Potentially eligible patients were screened by the research staff member based on reasons for the clinic visit, and were verified by the treating physician. Potentially eligible patients were approached by a member of the research team prior to meeting with the physician to discuss potential treatment options. The research staff member introduced the study using a core script and after making final eligibility determination based on an eligibility required that patients were those with AUB that had not yet been treated for their bleeding, had not previously been diagnosed or treated for AUB, did not have cancer within the past two years, were not pregnant, and could not have AUB due to a serious pelvic pathology (e.g. current or prior cancer) or due to medication use.

Additionally, eligible patients were age 18 or older and were potential candidates for either surgical or medical treatment. The diagnosis of AUB, the recommendation for treatment (including the requirement that patients were eligible for either medical or surgical interventions) were required to be verified by the treating physician for final study eligibility prior to randomization to avoid bias due to post-randomization eligibility exclusions.

After providing written informed consent, study participants completed a demographics questionnaire and the Symptom Severity Scale of the validated Uterine Fibroid Symptom Quality of Life (UFS-QOL) survey.(14) Patients were then centrally randomized via a simple 1:1 randomization method using SPSS random number generation. Randomization was stratified by clinic site, and patients were assigned to either the ACA survey or to usual counseling. Study staff and patients were blinded to the group allocation until after obtaining informed consent and completing the baseline surveys to minimize any potential bias in study enrollment. Those randomized to the ACA completed the survey prior to meeting with the physician for discussion of treatment alternatives, whereas patients randomized to usual counseling proceeded to meet with their physician for this discussion after completion of the baseline surveys. The ACA was presented to participants randomized to that group via a touchscreen computer. Participants in the ACA group answered a series of preference-based questions to elicit their values across each of the eight treatment attributes and through various combinations of those attributes. Immediately following completion of the ACA survey, the printed results were provided to the patient and the physician for use during the patient consult (Figure 1) along with a guide to interpretation of the results. Physicians were not blinded to those randomized to ACA for obvious reasons, but were not informed as to which of their

patients were enrolled to the study in the usual counseling group so as to not bias the discussion among the comparison group of study participants.

Approximately six weeks following the initial study visit, study participants were mailed two surveys to evaluate the primary study endpoints of treatment satisfaction and decision regret the Functional Assessment of Chronic Illness Therapy-Treatment Satisfaction-Patient Scale (FACT-TS-PS) and the Decision Regret Scale. Four subscales (interpersonal, decision making, trust and overall subscale) of the validated FACIT-TS-PS were used.(15) The Decision Regret Scale is a validated instrument that measures health care decision regret.(16) In cases of nonresponse to the initial mailing, reminder phone calls and up to three additional mailed copies of the surveys were sent prior to determining a patient to be lost to follow up. Participants were instructed to wait to complete the survey if treatment had not yet been received.

Sample size

It was determined that a sample size of 71 patients per group would allow the detection of a 10point mean difference on the Decision Regret Scale, with 80% power and a 0.05 level of significance, assuming a standard deviation of 21. A total sample size of 142 was therefore needed to have sufficient power to assess decision regret. The FACIT-TS-PS questionnaire items were combined into a continuous measure for overall satisfaction(15). A total of 286 participants were needed for 80% adequate power to detect a 7-point difference for two-tailed tests at the 0.05 level of significance. The study was designed to enroll 380 patients to account for a 20% anticipated non-response rate to have sufficient power for each endpoint analysis.

11

Data analysis

Data were analyzed using SPSS 15.0. All analyses were performed as intent-to-treat. Descriptive statistics were used to understand the demographic and clinical characteristics as well as the baseline survey responses, treatment choices and preference values of the overall study population. An individual score for the baseline UFS-QOL Symptom Severity Scale was calculated by summing the eight items. Higher scores reflect greater symptom severity, whereas lower scores indicate minimal symptom severity. Groups were compared using t-tests, chisquare analyses, and analysis of variance (ANOVA). In the case of a significant omnibus F-test in ANOVA, Tukey's post-hoc tests were conducted to control for multiple comparisons between subgroups. Exploratory analyses, which did not control for any potential confounding, were conducted to explore relationships in demographic subgroups for the purpose of hypothesis generation. Paired t-tests were used for the primary outcome analysis of decision regret and satisfaction by study group (ACA versus usual counseling). Regret scale scores range from 0 (no regret) to 100 (high regret). Scores for each item on the FACIT-TS-PS are summed for a total satisfaction score..

RESULTS

Three hundred and eighty-six women provided informed consent and enrolled in the study. Of these, seven were found to be ineligible and were not included in the study and five changed their mind about participating; resulting in a total of 374 eligible participants. Of these, 183 were randomized to the ACA survey and 191 were randomized to usual counseling (Figure 2). Eighty-three (22.2%) participants did not return the final surveys (23% in the ACA arm versus 21.5% in the control arm, p=0.80, Table 2) and were considered lost to follow up; study data

were complete for 291 eligible participants. There were no significant differences in the characteristics of patients lost to follow up versus those with complete data. Time to follow up was on average, 62 days, with a wide range of time from treatment selection to survey completion (38-177 days).

There were no differences in baseline characteristics or symptom severity between study groups (Table 2). There were no significant differences in symptom severity by race/ethnicity, insurance status, marital status, or education and there was no correlation between total symptom severity score and age (p=0.63).

Treatment selection

Two hundred and eighty-five participants provided information on the treatment they had selected for their AUB (Table 3). Differences in treatment choice between those randomized to ACA or usual counseling were small in magnitude and not statistically significant. The most common treatment choice was prescription medications such as oral contraceptives or hormone injection (n=123, 43.2%), followed by indecision (n=55, 19.3%) and hysterectomy (n=30, 10.5%). There were significant differences in treatment choice by both education (p=0.02) and racial/ethnic group (p=0.007), but not by age, or marital or insurance status. African American patients were more likely undecided about treatment at the time of follow up, and White patients were less likely than expected to be undecided about treatment at the time of follow up. Conversely, White participants were more likely to select prescription medications than African American patients. There were no differences between these groups with regard to the selection of IUD, ablation or hysterectomy. Patients with a college degree or more were more likely to

select prescription medication for care than those with a high school or some college education. There were no other differences by subgroup of educational attainment. There were no differences in treatment selection based on symptom severity score.

Patient Preferences

The preferences of patients randomized to ACA are presented in Table 4. The most important treatment attributes to study participants were treatment efficacy and the desire to minimize any impact on sexual function. The attributes that had the least value to participants in their decision making were if the treatment choice was permanent or if the treatment required taking pills.

There were a number of significant differences in treatment preferences based on the preplanned, exploratory analyses of demographic characteristics. Insurance status was significantly related to preference for cost of treatment (p=0.017), with the privately insured having a significantly lower value associated with costs than those supported by Medicaid or other subsidized insurance (p=0.045, adjusted for multiple comparisons). The importance of treatment efficacy (p=0.033) and the need to take pills (p=0.025) was significantly different by racial/ethnic group. At the subgroup level, treatment efficacy was no longer statistically significantly less likely to want to take pills every day as compared to African American (p=0.026) or White (p=0.014) participants (ANOVA post-hoc tests adjusted for multiple comparisons). Cost was also significantly different by education level (p=0.005), however, this was only significant at the subgroup level for those with only some high school education, who placed a significantly higher value on the cost of treatment than women with a college education (p=0.006, adjusted for multiple comparisons).

There were significant differences by age for preferences related to treatment efficacy (p=0.01), sexual function (p=0.05) and the impact on fertility (p<0.001) (ANOVA, by quartiles: 19-35; 35.1-41.8; 41.9-46.4; >46.4). Controlling for multiple comparisons, the second age quartile was less likely to place importance on treatment efficacy than the third quartile (p=0.008). Sexual function was significantly less important to the oldest quartile than the third quartile (p=0.04), and fertility was significantly more important to the youngest quartile than the second (p=0.047), third (p<0.001) and fourth quartile (p<0.001). Recovery time in post hoc tests was found to be was more important to the youngest quartile compared to the oldest quartile (p=0.04). There was no significant relationship between symptom severity and treatment preferences.

Post-hoc descriptive analyses explored the preferences of patients across the eight attributes of treatment options to understand whether the strength of values and preferences were consistent with treatment choice. Due to the small sample size across multiple treatment choices, the top four treatments selected by patients in the study (oral medications, IUD, ablation and hysterectomy) were used to explore the strength of preferences by treatment selected (Figure 3). Lower scores represent that the factor was of little value, whereas higher scores meant that the attribute was very important. While no significance testing could be conducted due to the small sample size, the attributes appear to be in accordance with what one might expect. For example, women who selected oral medications (Group A in Figure 3) valued their fertility, women who

selected hysterectomy (Group D in Figure 3) did not want to have to continue to visit their doctor regularly (a low value meant that this did not matter). Women selecting ablation or hysterectomy (Groups C and D) valued a treatment that worked right the first time (high efficacy). However, caution should be taken when interpreting these data and variability around each of the point estimates, as the varied confidence intervals are largely due to the small sample size of each group (other than the oral medication group, which was approximately half of the overall respondent group for this post-hoc analysis).

Satisfaction with Care

Satisfaction with care for the study population was high, with a mean score of 35.74 (SD: 9.72), out of a possible range of 0 to 44. Patients in the ACA group had equivalent satisfaction with care scores as those randomized to usual counseling (35.72, 95% CI: 34.0-37.4 versus 35.75, 95% CI: 34.2-37.3, p=0.98). There were also no differences in satisfaction by demographic characteristics or treatment selected.

Decision Regret

The average decision regret score in the study population was 25.9 (SD: 21.0). There was no difference between treatment regret by study group, with those randomized to ACA having a mean score of 25.1 (95% CI: 21.7-28.5) versus 26.7 (95% CI: 22.9-30.4) for usual counseling (p=0.54). There were no differences with decision regret scores by education, race/ethnicity, marital or insurance status. There was a highly significant inverse relationship between age and decision regret (p=0.007), with younger age associated with greater regret. There were significant differences in decision regret by the choice of treatment (p=0.01). Women who

underwent a hysterectomy had the lowest regret (mean decision regret score of 14.4), which was significantly different than those who received prescription medications (mean decision regret 28.0) or women who remained undecided about treatment (mean decision regret 31.8). There were no other differences in regret by treatment selected.

In the youngest quartile of patients (age 19-35) a 10-point difference in mean regret scores was observed for the ACA group versus usual counseling in the hypothesized direction (24.6 vs. 34.6, respectively, p = 0.08). Although this difference was not statistically significant, the small number of patients in this quartile (n=64) increases the likelihood of a Type II error.

DISCUSSION

There are several potential reasons why this randomized trial of a preference elicitation tool in a general sample of patients referred for AUB management did not detect differences in decision regret or satisfaction. Overall, regret was relatively low and satisfaction with care was high, suggesting that there was very little room for improvement in this population on the endpoints selected. In retrospect, while the primary aims were intended to assess satisfaction with the treatment selected, decisions were often not acted upon for many weeks following the counseling session due to various factors such as scheduling or the need for further tests. Therefore, the time point selected for follow up (e.g. 6 weeks after the study visit) is likely too far removed from the decision making process to accurately assess any remaining outcomes associated with the initial clinic visit. Despite the fact that the primary aims were not achieved in this study, there is considerable room for improved study designs and interventions using

ACA in the setting of AUB. For these reasons we believe that future studies will provide evidence supporting the use of ACA to support the treatment decision making process.

The use of ACA for preference elicitation is relatively new. In contradistinction to provision of information about the alternatives, ACA uses a structured protocol in which patients are prompted to consider and quantify what matters to them, and by how much. The resultant preference information allows both the patient and provider to know how the patient prioritizes the various attributes of treatment alternatives and may then be used as part of a decision support process, rather than being a decision aid in and of itself. Furthermore, the preference elicitation instrument is easily incorporated into clinical practice, as it is delivered via an internet-based survey and can be completed by patients in 15-20 minutes while waiting for their clinic appointment. Future studies should assess more proximal outcomes (e.g. satisfaction with the decision making process, not just the outcomes) among both patients and providers, and should keep records of the clinic time needed for counseling with and without the ACA tool, as these may prove to be meaningful endpoints of interest.

In addition to these lessons learned, additional information was obtained regarding the AUB population. The treatment choice analyses in this study found that prescription medications were the most commonly selected treatment alternative for AUB. While the results of the demographic subgroup analyses can only be considered a hypothesis generating, this was significantly higher among White women as compared to African American women who more often chose hysterectomy. Taking medications each day was also significantly less desirable to Hispanic women. The factors contributing to these different preferences is something that

should be studied in the future, and may help explain barriers or promoters against or for particular recommendations for care of AUB.

Hysterectomy as a treatment choice was associated with the lowest level of decision regret. This is consistent with improved satisfaction and less regret found in other populations, such as BRCA mutation carriers, who elect prophylactic surgery to reduce cancer risk.(17) It is possible that a decision such as hysterectomy, which cannot be reversed, was preceded with more thoughtful decision making. It is also possible that simply due to the selection of an irreversible option, patients have no other choice moving forward, while women who are being treated with hormone therapy may continue to wonder if surgery will be needed in the future. Future research should seek understand these factors to learn how to reduce decision regret for all treatment choices to levels found among women who underwent hysterectomy.

This study has several strengths. Participants represented a broad cross-section of women evaluating treatment options for AUB. The randomized, longitudinal design allowed for the comparison of ACA use apart from potential confounders and to determine its impact six weeks after the initial consultation. The use of validated measures for decision regret and treatment satisfaction allowed for greater precision for detecting a difference in outcomes. With 374 randomized participants, and final outcomes data available for 277 and 270 for satisfaction and decision regret, respectively, this study had ample statistical power to find a clinically important difference in both variables.

There are also several limitations. We recruited a diagnostic cross-section of women presenting to participating clinics with AUB of varied etiologies and may not be generalizable to specific diagnostic subgroups of AUB. Since risk factors for decision regret or treatment dissatisfaction in the setting of AUB were not established in other studies, study recruitment could not be limited to subsets of women at greatest risk. This resulted in a lack of statistical power to identify subgroups, such as younger women, who could be hypothesized to benefit most from the ACA. In addition, the ACA results were made available to physicians but did not require any documentation to verify their use of this tool. Therefore, there is incomplete knowledge of the true differences in counseling between the ACA and usual counseling groups that should be pursued in future research using ACA for AUB. Additionally, satisfaction and regret are multifactorial constructs that are influenced by many factors. Future work that wishes to retain the same study endpoints as in the present randomized trial may fist wish to explore the aspects of counseling and care that are associated with patient satisfaction and regret in the setting of AUB.

This study provides hypothesis generating data suggesting that higher decision regret may occur among the youngest quartile of study participants. While the regret score did not reach statistical significance by ACA or usual counseling (p=0.08), there were only 64 patients in this group and Type II error was likely. This is an intriguing finding, and suggests that future studies may wish to target those at greatest risk of decision regret who may potentially benefit from an intervention such as ACA. Age has been a contributing factor for decision regret in other conditions;(16,17) however, little data exist for women with AUB. Young patients may represent a population that should receive additional care in counseling for treatment decision making to reduce future regret. Further research should also address the relationship or possible clustering of preferences as well as the relationship between the strength of the preference and a patient's treatment decisions, as the current study was not powered or designed to assess these outcomes.

In conclusion, a preference-elicitation tool developed using ACA did not reduce decision regret or improve treatment satisfaction among patients with AUB presenting for an initial consultation visit. However, many lessons were learned about the study population, treatment selection, and approaches for future study design. Additionally, there is promise in the use of an approach such as ACA to aid the counseling process in settings such as AUB where treatment selection is largely based on patient preferences for care. There is a need for future work to continue to assess the value of this approach using study designs and considerations as discussed above.

REFERENCES

1. Matteson KA, Boardman LA, Munro MG, Clark MA. Abnormal uterine bleeding: a review of patient-based outcome measures. Fertility and sterility. 2009;92(1):205-16. Epub 2008/07/19.

2. Munro MG, Critchley HO, Fraser IS. The FIGO systems for nomenclature and classification of causes of abnormal uterine bleeding in the reproductive years: who needs them? American journal of obstetrics and gynecology. 2012. Epub 2012/03/06.

3. ACOG. Diagnosis of abnormal uterine bleeding in reproductive-aged women. Obstetrics & Gynecology. 2012;120(1):197-206.

4. Fraser IS, Langham, S., Uhl-Hochgraeber, K. Health-related quality of life and economic burden of abnormal uterine bleeding Expert Review of Obstetrics & Gynecology. 2009;4(2):179-89.

5. Liu Z, Doan QV, Blumenthal P, Dubois RW. A systematic review evaluating health-related quality of life, work impairment, and health-care costs and utilization in abnormal uterine bleeding. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2007;10(3):183-94. Epub 2007/05/30.

6. Munro MG, Critchley HO, Broder MS, Fraser IS. FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics. 2011;113(1):3-13. Epub 2011/02/25.

7. Green PE, Krieger, A. M., Agarwal, M.K. Adaptive conjoint analysis: Some caveats and suggestions. Journal of Marketing Research. 1991;28(2):215-22.

8. Fraenkel L, Gulanski B, Wittink D. Patient treatment preferences for osteoporosis. Arthritis and rheumatism. 2006;55(5):729-35. Epub 2006/10/03.

9. Fraenkel L, Rabidou N, Wittink D, Fried T. Improving informed decision-making for patients with knee pain. The Journal of rheumatology. 2007;34(9):1894-8. Epub 2007/08/19.

10. Langenhoff BS, Krabbe PF, Ruers TJ. Computer-based decision making in medicine: A model for surgery of colorectal liver metastases. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology. 2007;33 Suppl 2:S111-7. Epub 2007/12/07.

11. Pieterse AH, Stiggelbout AM, Baas-Thijssen MC, van de Velde CJ, Marijnen CA. Benefit from preoperative radiotherapy in rectal cancer treatment: disease-free patients' and oncologists' preferences. British journal of cancer. 2007;97(6):717-24. Epub 2007/09/13.

12. Longacre AV, Imaeda A, Garcia-Tsao G, Fraenkel L. A pilot project examining the predicted preferences of patients and physicians in the primary prophylaxis of variceal hemorrhage. Hepatology. 2008;47(1):169-76. Epub 2007/10/16.

13. Hess LM, Litwiller, A., Kasper, K., Stutsman, J., Byron, J., Learman, L. . Adaptive Conjoint Analysis as a Decision Aid for Dysfunctional Uterine Bleeding. . Society of Medical Decision Making Annual Meeting. 2010.

14. Spies JB, Coyne K, Guaou Guaou N, Boyle D, Skyrnarz-Murphy K, Gonzalves SM. The UFS-QOL, a new disease-specific symptom and health-related quality of life questionnaire for leiomyomata. Obstetrics and gynecology. 2002;99(2):290-300. Epub 2002/01/30.

15. Cella D, Hahn, E., Webster, K., Eremenco, S., Lent, L., Hudges, S., Beaumont, J., Shonk, C. The FACIT treatment satisfaction measurement system. JSTOR: Quality of Life Research. 2003;12(7):747.

16. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a decision regret scale. Medical decision making : an international journal of the Society for Medical Decision Making. 2003;23(4):281-92. Epub 2003/08/21.

17. Westin SN, Sun CC, Lu KH, Schmeler KM, Soliman PT, Lacour RA, et al. Satisfaction with ovarian carcinoma risk-reduction strategies among women at high risk for breast and ovarian carcinoma. Cancer. 2011;117(12):2659-67. Epub 2011/06/10.

Figure legends

Figure 1. Example patient/provider printout showing individual patient preference results from the adaptive conjoint analysis (ACA) survey regarding attributes of treatment for abnormal uterine bleeding (AUB)

Figure 2. CONSORT flow diagram

Figure 3. Preferences of treatment attributes (mean and 95% confidence interval) by the four most common treatments selected: A-oral medications; B-intrauterine device (IUD); C-ablation; D-hysterectomy (n=90)

Attribute	Levels	Descriptor	
Treatment success	3	How effective is the treatment	
Sexual function	3	What is the impact on sexual function	
Medical care	3	Where does the treatment take place	
Cost	4	Cost of the treatment	
Fertility	4	What is the impact on fertility	
Oral medications	3	Frequency of oral medication use	
Permanence	2	Can the treatment outcome be reversed or is it permanent	
Recovery time	3	What is the recovery time	

Table 1. Attributes and levels used in the adaptive conjoint analysis survey

 Table 2. Demographic and clinical characteristics

	Adaptive	Usual counseling	p-value		
	Conjoint	(n=191)			
	Analysis (n=183)				
Age – mean (SD)	41.2 (7.9)	40.8 (8.3)	0.63		
Education – n (%)					
8 th grade or less	4 (2.1%)	4 (2.1%)			
Some high school	22 (12.0%)	31 (16.2%)			
High school graduate/GED	63 (34.4%)	62 (32.5%)	0.75		
Some college/technical school	53 (29.0%)	58 (30.4%)			
College graduate	41 (22.4%)	36 (18.8%)	1		
Marital status – n (%)					
Married/cohabitating	82 (44.8%)	88 (49.2%)			
Divorced/separated	51 (27.9%)	45 (23.6%)	0.74		
Widowed	3 (1.6%)	5 (2.6%)	0.74		
Never married	47 (25.7%)	53 (27.7%)			
Race/Ethnicity – n (%)					
White, non-Hispanic	86 (47.0%)	94 (49.2%)			
African American	85 (46.4%)	80 (41.9%)	0.57		
Hispanic	8 (4.4%)	11 (5.8%)	1		

Native American	3 (1.6%)	4 (2.1%)		
Asian	0 (0%)	2 (1.0%)		
Insurance status				
Insured (Private)	141 (77.0%)	153 (80.1%)		
Insured (Public/Subsidized)	34 (18.6%)	29 (15.2%)	0.68	
Uninsured	8 (4.4%)	9 (4.7%)		
Symptom burden – mean (SD) ^a	29.79 (6.40)	29.76 (6.47)	0.97	
Days to follow up assessment –	60.1 (21.4)	64.3 (24.9)	0.16	
mean (SD)				
Lost to follow up - n (%)	42 (23.0%)	41 (21.5%)	0.80	

^a USF-QOL Symptom Severity Scale, possible range 8-40

Table 3. Treatment choice, by study group*

Treatment choice	Adaptive	Usual counseling
	Conjoint Analysis	(n=145)
	(n=140)	
Prescription medication	63 (45%)	60 (41.4%)
Intrauterine device (IUD)	6 (4.3%)	5 (3.4%)
Endometrial ablation	14 (10.0%)	9 (6.3%)
Hysterectomy	13 (9.3%)	17 (11.7%)
Not decided	29 (20.7%)	26 (17.9%)
Declined treatment	8 (5.7%)	12 (8.3%)
Other	7 (5.0%)	16 (11.0%)

* None of the choices were significantly different between groups

Attribute	Mean (SD)	95% CI
	(Possible range = $0-35$)	
Treatment efficacy	15.6 (5.8)	14.9-16.5
Impact on sexual function	13.7 (6.1)	12.9-14.7
Cost	13.7 (5.3)	13.0-14.5
Need for additional medical	13.3 (5.5)	12.5-14.1
visits		
Impact on fertility	12.2 (5.8)	11.3-13.0
Recovery time	11.2 (4.8)	10.5-11.9
Need to take pills	10.2 (5.5)	9.4-11.0
Permanence of treatment choice	10.0 (5.5)	9.2-10.8

Table 4. Mean attribute importance values (n=183)