Construct domain analysis of patient health-related quality of life: physical and mental trajectory profiles following open versus endovascular repair of abdominal aortic aneurysm

Purpose: Many clinical trials comparing the outcomes of open surgical repair (OSR) versus endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAAs) have been conducted, with varying results. Surprisingly, few outcomes studies have closely examined perceived physical and mental health-related quality of life (HRQOL) factors through a validated survey tool. The purpose of this prospective observational study was to describe the trajectory of HRQOL measures, from baseline to 1 year after surgery, in patients undergoing OSR or EVAR for AAA, and to explore for differences in physical and mental composite scores and their construct domains (subscales) using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36®) tool.

Patients and methods: Over an 18-month period, a small sample of patients undergoing elective AAA repair in a community hospital setting were prospectively enrolled. Fifteen patients undergoing OSR and twenty patients undergoing EVAR were studied. Physical and mental HRQOL parameters were assessed using the SF-36.

Results: No significant differences in demographic and clinical variables were found between the OSR and EVAR groups. In the multivariable linear models with repeated measures, both groups showed a significant decline in physical health composite scores 30 days after the surgical procedure (P<0.01). However, although the OSR group showed a statistically significant decline in three of the four physical health domains, the EVAR group declined in only one physical health domain. Only the OSR group showed a significant decline in three of the four mental health domains at 30 days; however, the decline of these domains was not reflected in the group’s mental health composite scores. By 90 days after surgery, both groups were not significantly different from their baseline in physical or mental health composite scores, or in any of their respective physical health domains.

Conclusion: In this small sample of patients undergoing AAA repair, EVAR resulted in less physical and emotional decline than OSR in the early postoperative period. However, patients in both groups may return to near baseline status at 90 days.

Keywords: AAA, endovascular aneurysm repair (EVAR), open surgical repair (OSR), Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36®), health related quality of life (HRQ)

Introduction
The prevalence of diagnosed abdominal aortic aneurysm (AAA) in the United States, determined by various methods, is estimated to be between 19% and 24% for women and between 66% and 81% for men. Approximately 15,000 deaths per year are caused
by ruptured AAAs and dissections; the number may be as high as 30,000 if undiagnosed cases resulting in sudden death are considered.23

Conventional open surgical repair (OSR) for AAA was first performed in 1951. With the evolution of surgical techniques and aggressive critical care, the perioperative mortality rate ranges from 2% to 6%.47 In 1991, Parodi et al8 introduced endovascular abdominal aortic aneurysm repair (EVAR), a minimally invasive intervention. This technique has gained wide acceptance in patients with favorable anatomic features and/or in those in whom the surgical stress of the traditional open repair is prohibitive.8

Many clinical trials have been conducted comparing OSR and EVAR outcomes of morbidity and mortality, with varying results.9 Surprisingly, few outcomes studies have closely examined perceived physical and mental health-related quality of life (HRQOL) factors through a validated survey tool following OSR and EVAR.10–13 When discussing the advantages of one procedure over the other with prospective patients, the impact on postoperative HRQOL may be important. As such, the present authors became interested in better understanding the association of each surgical procedure with physical and mental HRQOL, as well as aiming to better delineate how these surgical procedures for AAA repair affect the time course of recovery with respect to perceived HRQOL.

The purpose of this prospective observational study was to describe the trajectory of HRQOL measures from baseline to 1 year after AAA repair in patients undergoing OSR or EVAR, and to explore for differences in physical and mental health composite scores and their construct domains (subscales) using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36®) tool.16–18

Material and methods

General study design

Over an 18-month period, 35 consecutive patients undergoing elective AAA repair in a community hospital setting were prospectively enrolled in this study. The Institutional Review Board at Saint Joseph Mercy Health System approved the investigation, and each participant gave fully informed written consent before enrollment.

Physical and mental HRQOL parameters were assessed using the SF-36 (Medical Outcomes Trust, Inc, Waltham, MA, USA).16–18 This survey is a validated tool that generically assesses two major dimensions providing two composite scores: (1) physical health composite score, constructed from the four domains of physical function (PF), role physical (ie, role limitations due to physical function, RP), bodily pain (BP), and general health, and (2) mental health composite score, constructed from the four domains of vitality (VT), social function (SF), role emotional (ie, role limitations due to emotional health, RE), and mental health (MH) (Table 1).

Patients completed the SF-36 surveys at their preadmission visit and then postoperatively at 30, 90, and 365 days. During the follow-up period, the questionnaire was mailed to each patient’s home approximately 1 week prior to when it was required to be completed, and this was sent with a request to have the questionnaire returned within 1 week via a prepaid postage return envelope. A research nurse telephoned each participant to assess his or her progress with completing the questionnaire and to ensure the form’s timely return.

Five board-certified vascular surgeons performed the AAA surgical repairs. The surgical procedure chosen was at the discretion of the surgeon and was based on patient suitability, anatomic favorability, associated comorbidities, and patient acceptance.

Statistical methods

Demographic and baseline variables were summarized using the mean plus or minus standard deviation or the percentage with 95% confidence interval, as indicated. Univariate associations of demographic and clinical variables with surgical procedure were examined using the Wilcoxon rank sum test for continuous variables and chi-square or Fisher’s exact test for categorical variables.

Analyses were performed using SAS® software (v 9.1; SAS Institute Inc, Cary, NC, USA). Multivariable linear

Table 1 Brief explanation of physical and mental health domains

<table>
<thead>
<tr>
<th>Domain</th>
<th>Brief definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical health</td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
<td>Limitations in all (even simple) physical activities due to health problems</td>
</tr>
<tr>
<td>Role physical</td>
<td>Limitations in work or daily activities due to physical health</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>Limitations due to severe bodily pain</td>
</tr>
<tr>
<td>General health</td>
<td>Perceived personal health</td>
</tr>
<tr>
<td>Mental health</td>
<td></td>
</tr>
<tr>
<td>Vitality</td>
<td>Feelings of vitality, from tired to energetic</td>
</tr>
<tr>
<td>Social function</td>
<td>Limitations with social activities due to physical and emotional problems</td>
</tr>
<tr>
<td>Role emotional</td>
<td>Problems with work or daily activities due to emotional problems</td>
</tr>
<tr>
<td>Mental health</td>
<td>Feelings of depression, nervousness – general mental health</td>
</tr>
</tbody>
</table>

Note: Higher scores indicate fewer limitations or problems.
models with repeated measures (PROC MIXED; SAS Institute Inc) were used to investigate whether the association of physical and mental health component summary scores of the SF-36 with surgical procedure over time differed between treatment groups. An unstructured covariance matrix was specified. Baseline covariates were not included in the models since the uncorrected trajectory of scores over time were of interest, understanding that the two groups were probably different by virtue of the surgery selection process. Residual and Q-Q plots were monitored to check the assumptions of linear modeling. The statistical significance between groups and at different time points was determined using least square mean differences. All P-values were corrected for multiple comparisons using the Tukey-Kramer method.

**Results**

Thirty-five patients were studied, with 15 patients (42.9%) undergoing an OSR and 20 patients (57.1%) undergoing an EVAR. Eleven patients in the OSR group (73.3%) and 15 patients in the EVAR group (75%) completed all three follow-up visits. The mean age for all patients was 69.9 ± 6.5 years. Only three of the patients (8.6%) were women.

Patient baseline clinical characteristics for each group are shown in Table 2. No significant differences in demographic and clinical variables were demonstrated between the OSR and EVAR groups.

Baseline mean SF-36 measurements for the physical and mental health composite scores and subscales (domains) that make up each composite score are shown in Figure 1, along with normative values for visual comparison.17,18 There were no statistically significant baseline differences in any of the physical or mental health domain scores between the OSR and the EVAR groups. In the EVAR group, there was a trend to lower mean scores for the domains of PF, RP, and general health. However, none of these differences between study groups were statistically significant. In the repeated measures analysis, baseline physical health composite scores were significantly lower in the EVAR group than in the OSR group (P < 0.05), after correction for multiple comparisons.

The SF-36 physical and mental health composite and domain scores over time are demonstrated in Table 3. In the multivariable linear models with repeated measures, both OSR and EVAR groups showed a significant decline in physical health composite scores 30 days after the surgical procedure (P < 0.01 and P < 0.01, respectively). The OSR group showed a statistically significant decline in three of the four physical health domains (PF, P < 0.01; RP, P < 0.01; BP, P < 0.01) while the EVAR group declined in only one physical health domain (BP, P < 0.05). Both groups were not significantly different from their baseline by 90 days after the surgery in their physical health composite scores or in any of the respective physical health domains. Regarding mental health composite scores, the OSR group showed a statistically significant decline in three of four mental health domains (VT, P < 0.01; SF, P < 0.01; MH, P < 0.01) at 30 days, but the decline of these domains was not reflected in the OSR group’s mental health composite score. Importantly,

**Table 2** Demographic, clinical, and baseline variables for all patients, and for patients by surgical procedure

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patients (n = 35)</th>
<th>OSR group (n = 15)</th>
<th>EVAR group (n = 20)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)a</td>
<td>69.9 ± 6.5</td>
<td>69.2 ± 3.8</td>
<td>70.5 ± 8.0</td>
<td>0.74</td>
</tr>
<tr>
<td>Maleb</td>
<td>91 (75–98)</td>
<td>93 (66–100)</td>
<td>90 (67–98)</td>
<td>1.00</td>
</tr>
<tr>
<td>Marrieda</td>
<td>77 (59–89)</td>
<td>87 (59–98)</td>
<td>70 (46–87)</td>
<td>0.60</td>
</tr>
<tr>
<td>Smokerc</td>
<td>80 (63–91)</td>
<td>80 (51–95)</td>
<td>80 (55–93)</td>
<td>1.00</td>
</tr>
<tr>
<td>Years smokedd</td>
<td>29.7 ± 18.5</td>
<td>28.2 ± 16.8</td>
<td>30.8 ± 20.0</td>
<td>0.53</td>
</tr>
<tr>
<td>Family history of AAAe</td>
<td>9 (2–25)</td>
<td>7 (0–34)</td>
<td>10 (2–33)</td>
<td>1.00</td>
</tr>
<tr>
<td>Coronary artery diseased</td>
<td>51 (34–68)</td>
<td>47 (23–73)</td>
<td>55 (32–76)</td>
<td>0.63</td>
</tr>
<tr>
<td>Hypertensionf</td>
<td>54 (37–71)</td>
<td>53 (27–77)</td>
<td>55 (32–76)</td>
<td>1.00</td>
</tr>
<tr>
<td>Diabetesf</td>
<td>14 (5–31)</td>
<td>20 (5–49)</td>
<td>10 (2–33)</td>
<td>0.63</td>
</tr>
<tr>
<td>Cancerf</td>
<td>26 (13–44)</td>
<td>27 (9–55)</td>
<td>25 (10–49)</td>
<td>1.00</td>
</tr>
<tr>
<td>Cerebral vascular diseased</td>
<td>9 (2–25)</td>
<td>0 (0–27)</td>
<td>15 (2–35)</td>
<td>0.25</td>
</tr>
<tr>
<td>Previous vascular surgeryf</td>
<td>3 (0–17)</td>
<td>0 (0–25)</td>
<td>5 (4–27)</td>
<td>1.00</td>
</tr>
<tr>
<td>COPDf</td>
<td>20 (9–37)</td>
<td>13 (2–41)</td>
<td>25 (10–49)</td>
<td>0.67</td>
</tr>
<tr>
<td>Hysterectomy, prostate, or testicular surgeryf</td>
<td>26 (13–44)</td>
<td>20 (5–49)</td>
<td>30 (13–54)</td>
<td>0.70</td>
</tr>
</tbody>
</table>

Notes: *Data presented as mean plus or minus standard deviation; data presented as percentage (95% confidence interval). Abbreviations: OSR, open surgery repair; EVAR, endovascular aneurysm repair; AAA, abdominal aortic aneurysm; COPD, chronic obstructive pulmonary disease.
all mental health domain scores returned to baseline values at 90 days, as was seen in the physical health measures.

Discussion
In clinical trials randomizing patients to elective OSR or EVAR, postoperative outcomes for morbidity and mortality have been similar at 1 year.\textsuperscript{10,19–21} As a disease of the elderly, patients with AAA often have major comorbidities, and EVAR, as a less invasive procedure, may be the perceived procedure of choice. In contrast, OSR may be preferred if the anatomy of the aneurysm precludes EVAR, as well as in some emergency situations. In other cases the choice of surgical procedure may depend on how the surgeon interprets the current surgical literature, his or her professional experience with the procedures, and, possibly, the patient’s perceived physical and mental HRQOL following the surgical technique for AAA repair.

In this study, which represents surgical decision making in a real-world, community hospital setting, it was shown that patients who were selected for EVAR had a trend to lower baseline SF-36 physical health composite scores than those undergoing OSR. This may reflect the clinical decision to prefer EVAR over OSR in patients with poorer health, who may be at a greater risk for complications from open repair.

AAA repair physical health composite scores were substantially reduced 30 days postoperatively for both OSR and EVAR groups. The scores returned to baseline levels for both groups by 90 days, and remained so at 1 year. Neither surgical procedure resulted in changes in the mental health composite scores. These findings were similar to those reported in the randomized EVAR-1 trial, in which physical health composite scores were lower than baseline for the OSR

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**Table 3 Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36\textsuperscript{®}) physical and mental health composite scores and their respective domain scores by procedure and time**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Follow-up time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>Open surgical repair, baseline SF-36 variable</td>
<td></td>
</tr>
<tr>
<td>Overall physical health composite scores</td>
<td>50.3 (7.8)</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>82.7 (18.0)</td>
</tr>
<tr>
<td>Role physical</td>
<td>71.7 (45.2)</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>85.9 (23.9)</td>
</tr>
<tr>
<td>General health</td>
<td>72.0 (20.7)</td>
</tr>
<tr>
<td>Overall mental health composite scores</td>
<td>49.9 (9.2)</td>
</tr>
<tr>
<td>Vitality</td>
<td>64.0 (17.1)</td>
</tr>
<tr>
<td>Social function</td>
<td>83.3 (21.5)</td>
</tr>
<tr>
<td>Role emotional</td>
<td>75.6 (38.8)</td>
</tr>
<tr>
<td>Mental health</td>
<td>75.8 (16.7)</td>
</tr>
<tr>
<td>Endovascular repair, baseline SF-36 variable</td>
<td></td>
</tr>
<tr>
<td>Overall physical health composite scores</td>
<td>42.0 (7.5)</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>66.6 (16.6)</td>
</tr>
<tr>
<td>Role physical</td>
<td>51.3 (41.7)</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>80.8 (19.5)</td>
</tr>
<tr>
<td>General health</td>
<td>57.7 (20.3)</td>
</tr>
<tr>
<td>Overall mental health composite scores</td>
<td>52.8 (8.2)</td>
</tr>
<tr>
<td>Vitality</td>
<td>56.8 (19.8)</td>
</tr>
<tr>
<td>Social function</td>
<td>80.6 (20.1)</td>
</tr>
<tr>
<td>Role emotional</td>
<td>78.3 (34.7)</td>
</tr>
<tr>
<td>Mental health</td>
<td>79.5 (12.6)</td>
</tr>
</tbody>
</table>

Notes: \textsuperscript{a}Statistically different from baseline, using the Tukey-Kramer method of correction for multiple comparisons. Data presented as mean plus or minus standard deviation.
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Disclosure
NJM and WMW were involved in the study conception and design. NJM, SWL, JVM, RML, and WMW performed the analysis and interpretation. NJM, SWL, and RML collected the data. NJM, SWL, and RML drafted the manuscript and BGH and WMW provided supervision. All authors read and approved the final manuscript.

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References