Costs, quality of life and cost-effectiveness of open and arthroscopic repair for rotator cuff tears: economic evaluation alongside the UKUFF trial

SUPPLEMENTARY INFORMATION

This supplementary information contains further details of:

- The proportion of responses at each level the five EQ-5D domains, before and after imputation (Table 1 and Table 2 respectively).
- Results of the economic analysis on a per-protocol basis, i.e. for only those patients who actually received the type of repair they were allocated to (arthroscopic or open repair). Resource use (Table 3), costs (Table 4), quality of life (Table 5), incremental cost-effectiveness (Table 6), and uncertainty using bootstrapping (Figure a and Figure b) are presented. Note that this analysis excludes patients in each of the randomisation groups who received procedures other than those they were allocated to (e.g. sub-acromial decompression, repair of another type, etc.). Results were produced using imputed data.

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Table 1: Number (%) of responses for each level in each domain of the EQ-5D questionnaire – non-imputed data (N=273)

| | Baseline | | | | | | At 8 months of follow-up | | | | |
|----------------|----------|-----------|----------|----------|----------|----------|--------------------------|----------|----------|----------|--|
| Response level | Mobility | Self-care | Activity | Pain | Anxiety | Mobility | Self-care | Activity | Pain | Anxiety | |
| 1 | 215 (79) | 154 (56) | 39 (14) | 7 (3) | 183 (67) | 189 (69) | 181 (66) | 105 (38) | 63 (23) | 165 (60) | |
| 2 | 57 (21) | 117 (43) | 218 (80) | 197 (72) | 80 (29) | 57 (21) | 59 (22) | 128 (47) | 164 (60) | 72 (26) | |
| 3 | | 2 (1) | 16 (6) | 69 (25) | 9 (3) | | 5 (2) | 14 (5) | 19 (7) | 8 (3) | |
| N/A (died) | | | | | | 1 (0) | 1 (0) | 1 (0) | 1 (0) | 1 (0) | |
| Missing | 1 (0) | | | | 1 (0) | 26 (10) | 27 (10) | 25 (9) | 25 (9) | 27 (10) | |

(contd.)

| | At 12 months of follow-up | | | | | | At 24 months of follow-up | | | | |
|----------------|---------------------------|-----------|----------|----------|----------|----------|---------------------------|----------|----------|----------|--|
| Response level | Mobility | Self-care | Activity | Pain | Anxiety | Mobility | Self-care | Activity | Pain | Anxiety | |
| 1 | 177 (65) | 192 (70) | 124 (45) | 84 (31) | 179 (66) | 166 (61) | 196 (72) | 135 (49) | 91 (33) | 180 (66) | |
| 2 | 64 (23) | 48 (18) | 108 (40) | 141 (52) | 57 (21) | 68 (25) | 36 (13) | 94 (34) | 135 (49) | 50 (18) | |
| 3 | 1 (0) | 3 (1) | 13 (5) | 19 (7) | 6 (2) | | 2(1) | 5 (2) | 8 (3) | 4(1) | |
| N/A (died) | 1 (0) | 1 (0) | 1 (0) | 1 (0) | 1 (0) | 3 (1) | 3 (1) | 3 (1) | 3 (1) | 3 (1) | |
| Missing | 30 (11) | 29 (11) | 27 (10) | 28 (10) | 30 (11) | 36 (13) | 36 (13) | 36 (13) | 36 (13) | 36 (13) | |

Table 2: Percentage (SE) of responses for each level in each domain of the EQ-5D questionnaire – imputed data (N=273)

| | Baseline | | | | | | At 8 months of follow-up | | | | | |
|----------------|------------|------------|------------|------------|------------|------------|--------------------------|------------|------------|------------|--|--|
| Response level | Mobility | Self-care | Activity | Pain | Anxiety | Mobility | Self-care | Activity | Pain | Anxiety | | |
| 1 | 79.0 (2.5) | 56.4 (3.0) | 14.3 (2.1) | 2.6 (1.0) | 67.3 (2.8) | 76.3 (2.7) | 73.2 (2.8) | 42.2 (3.1) | 25.6 (2.8) | 67.5 (3.0) | | |
| 2 | 21.0 (2.5) | 42.9 (3.0) | 79.9 (2.4) | 72.2 (2.7) | 29.4 (2.8) | 23.3 (2.7) | 24.5 (2.7) | 51.8 (3.2) | 66.5 (3.0) | 29.0 (2.9) | | |
| 3 | | 0.7 (0.5) | 5.9 (1.4) | 25.3 (2.6) | 3.3 (1.1) | | 1.9 (0.8) | 5.6 (1.5) | 7.5 (1.6) | 3.1 (1.1) | | |
| N/A (died) | | | | | | 0.4 (0.4) | 0.4 (0.4) | 0.4 (0.4) | 0.4 (0.4) | 0.4 (0.4) | | |
| Missing | 79.0 (2.5) | 56.4 (3.0) | 14.3 (2.1) | 2.6 (1.0) | 67.3 (2.8) | 76.3 (2.7) | 73.2 (2.8) | 42.2 (3.1) | 25.6 (2.8) | 67.5 (3.0) | | |

(Table 2 contd.)

| | At 12 months of follow-up | | | | | | At 24 months of follow-up | | | | | | |
|----------------|---------------------------|------------|------------|------------|-------------|------------|---------------------------|------------|------------|------------|--|--|--|
| Response level | Mobility | Self-care | Activity | Pain | Anxiety | Mobility | Self-care | Activity | Pain | Anxiety | | | |
| 1 | 72.6 (2.9) | 78.3 (2.6) | 50.7 (3.1) | 34.4 (3.0) | 73.7 (2.7) | 68.9 (2.9) | 81.6 (2.5) | 56.3 (3.2) | 38.4 (3.1) | 75.4 (2.8) | | | |
| 2 | 26.5 (2.9) | 20.2 (2.6) | 43.7 (3.1) | 57.3 (3.1) | 23.4 (26.6) | 30.0 (2.9) | 16.4 (2.4) | 40.2 (3.2) | 56.3 (3.2) | 21.7 (2.6) | | | |
| 3 | 0.5 (0.5) | 1.2 (0.7) | 5.3 (1.4) | 8.0 (1.7) | 2.5 (1.0) | | 0.9 (0.6) | 2.4 (1.0) | 4.2 (1.4) | 1.8 (0.9) | | | |
| N/A (died) | 0.4 (0.4) | 0.4 (0.4) | 0.4 (0.4) | 0.4 (0.4) | 0.4 (0.4) | 1.1 (0.6) | 1.1 (0.6) | 1.1 (0.6) | 1.1 (0.6) | 1.1 (0.6) | | | |

Table 3: Resource use outcomes for follow-up, per-protocol analysis using imputed data

| Mean resource use | Arthroscopic | Open | Arthroscopic vs. Open | Arthroscopic vs. Open |
|--|-------------------|-------------------|---|--|
| | N=63 mean (SE) | N=85 mean (SE) | mean difference (CI; p-value) [no covariate adjustment] | mean difference (CI; p-value) [adjusting for Age, Tear Size, Centre] |
| Revision surgery between surgery and 12 months | 0 (-) | 0.01 (0.01) | -0.01 (-0.04 , 0.02; 0.391) | -0.01 (-0.04, 0.01; 0.327) |
| GP visits between surgery and 12 months | 1.0 (0.2) | 1.4 (0.2) | -0.3 (-1.0 , 0.4; 0.356) | -0.2 (-0.9 , 0.5; 0.567) |
| Nurse visits between surgery and 12 months | 0.5 (0.2) | 0.8 (0.2) | -0.3 (-0.9 , 0.3; 0.308) | -0.4 (-1.0 , 0.3; 0.251) |
| Physiotherapist visits between surgery and 12 months | 7.7 (0.8) | 8.0 (0.7) | -0.3 (-2.2 , 1.8; 0.800) | 0.4 (-1.7 , 2.4; 0.728) |
| Inpatient visits between surgery and 12 months | 0.5 (0.2) | 0.6 (0.2) | -0.2 (-0.7 , 0.4; 0.596) | -0.3 (-0.9, 0.3; 0.373) |
| Outpatient visits between surgery and 12 months | 1.9 (0.3) | 2.9 (0.5) | -1.0 (-2.2 , 0.2; 0.111) | -0.7 (-1.9 , 0.6; 0.283) |
| Revision surgery between 12 and 24 months | 0.03 (0.02) | 0.04 (0.02) | 0.00 (-0.06, 0.06; 0.907) | -0.01 (-0.08, 0.06; 0.777) |
| GP visits between 12 and 24 months | 0.4 (0.2) | 0.4 (0.2) | 0.0 (-0.5 , 0.4; 0.936) | 0.1 (-0.5 , 0.5; 0.981) |
| Nurse visits between 12 and 24 months | 0.0 (0.0) | 0.1 (0.1) | -0.1 (-0.2 , 0.1; 0.369) | -0.1 (-0.2 , 0.1; 0.388) |
| Physiotherapist visits between 12 and 24 months | 1.9 (1.0) | 0.7 (0.3) | 1.3 (-0.5 , 3.0; 0.165) | 1.4 (-0.4 , 3.2; 0.116) |
| Inpatient visits between 12 and 24 months | 0 (-) | 0(-) | NA | NA |
| Outpatient visits between 12 and 24 months | 0.5 (0.3) | 0.3 (0.1) | 0.2 (-0.3 , 0.7; 0.488) | 0.2 (-0.2 , 0.7; 0.334) |

Table 4: Cost outcomes for follow-up, per-protocol analysis using imputed data

| Mean cost | Arthroscopic | Open | Arthroscopic vs. Open | Arthroscopic vs. Open |
|--|--------------|------------|-------------------------------|--|
| | N=63 | N=85 | mean difference (CI; p-value) | mean difference (CI; p-value) |
| | mean (SE) | mean (SE) | [no covariate adjustment] | [adjusting for Age, Tear Size, Centre] |
| Revision surgery between surgery and 12 months | 0 (-) | 4 (4) | -4 (-13 , 5; 0.391) | -5 (-15 , 5; 0.327) |
| GP visits between surgery and 12 months | 38 (9) | 50 (9) | -12 (-37 , 13; 0.356) | -8 (-35 , 19; 0.567) |
| Nurse visits between surgery and 12 months | 5 (2) | 9 (2) | -3 (-10 , 3; 0.308) | -4 (-11 , 3; 0.245) |
| Physiotherapist visits between surgery and 12 months | 337 (33) | 348 (29) | -11 (-99 , 76; 0.800) | 16 (-73 , 105; 0.728) |
| Inpatient visits between surgery and 12 months | 181 (74) | 240 (78) | -59 (-278 , 160; 0.596) | -103 (-333 , 126; 0.373) |
| Outpatient visits between surgery and 12 months | 313 (54) | 469 (74) | -157 (-350 , 37; 0.111) | -111 (-315 , 93; 0.283) |
| Medication costs between surgery and 12 months | 7 (2) | 5 (1) | 1 (-3, 6; 0.529) | 1 (-3 , 5; 0.662) |
| Cost after surgery to 12 month follow-up | 881 (109) | 1126 (131) | -245 (-599 , 109; 0.174) | -215 (-583 , 154; 0.251) |
| Total cost over 12 months | 3343 (141) | 3217 (159) | 126 (-316, 569; 0.573) | 100 (-340 , 540; 0.653) |
| Revision surgery between 12 and 24 months | 65 (46) | 50 (35) | 16 (-96 , 127; 0.782) | 9 (-114 , 132; 0.882) |
| GP visits between 12 and 24 months | 15 (6) | 15 (6) | -1 (-17, 16; 0.936) | 0 (-18, 18; 0.981) |
| Nurse visits between 12 and 24 months | 0 (0) | 1 (1) | -1 (-2 , 1; 0.369) | -1 (-2 , 1; 0.388) |
| Physiotherapist visits between 12 and 24 months | 84 (43) | 29 (12) | 55 (-23 , 132; 0.165) | 63 (-16 , 142; 0.116) |
| Inpatient visits between 12 and 24 months | 0 (–) | 0 (–) | NA | NA |
| Outpatient visits between 12 and 24 months | 82 (44) | 53 (17) | 30 (-55 , 115; 0.488) | 39 (-40 , 118; 0.334) |
| Total cost from 12 to 24 months | 247 (119) | 148 (46) | 99 (-128 , 327; 0.391) | 110 (-126 , 347; 0.357) |
| Total cost over 24 months | 3590 (226) | 3365 (171) | 226 (-330 , 781; 0.423) | 210 (-342 , 763; 0.452) |
| Total cost over 24 months (time-discounted) | 3582 (223) | 3360 (171) | 222 (-328 , 773; 0.426) | 207 (-341 , 754; 0.456) |

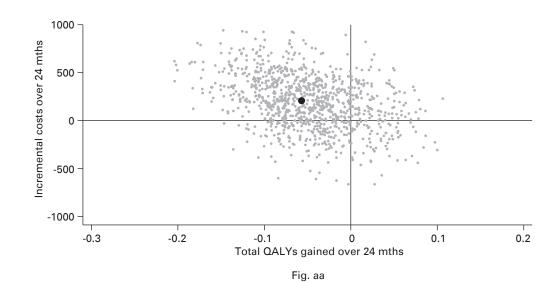
Table 5: Quality of life outcomes: quality-adjusted life years, per protocol analysis using imputed data

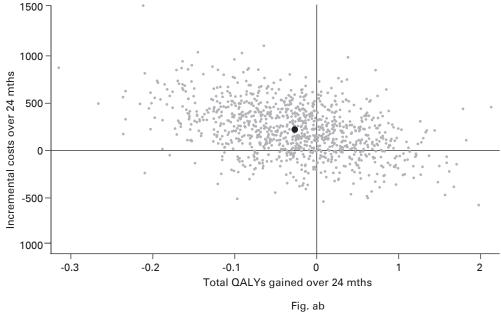
| Mean total QALYs | Arthroscopic | Open | Arthroscopic vs. Open | Arthroscopic vs. Open |
|---|--------------|-------------|--------------------------------------|--------------------------------------|
| | N=63 | N=85 | mean difference (CI; p-value) | mean difference (CI; p-value) |
| | mean (SE) | mean (SE) | [base case, no covariate adjustment] | [adjusting for baseline EQ-5D index] |
| Quality of life | | | | |
| EQ-5D_index_BL | 0.53 (0.04) | 0.50 (0.03) | 0.03 (-0.07, 0.13; 0.579) | NA |
| EQ-5D_index_8mo | 0.67 (0.04) | 0.70 (0.03) | -0.03 (-0.13 , 0.06; 0.519) | -0.04 (-0.13 , 0.04; 0.326) |
| EQ-5D_index_12mo | 0.71 (0.04) | 0.72 (0.03) | -0.00 (-0.10 , 0.09; 0.952) | -0.01 (-0.10 , 0.08; 0.786) |
| EQ-5D_index_24mo | 0.74 (0.03) | 0.78 (0.02) | -0.04 (-0.12 , 0.04; 0.353) | -0.05 (-0.12 , 0.03; 0.256) |
| Results for participants treated per-protocol | | | | |
| QALYs from baseline to 8mo | 0.40 (0.02) | 0.40 (0.02) | 0.00 (-0.06, 0.05; 0.964) | -0.01 (-0.04, 0.01; 0.326) |
| QALYs from 8mo to 12mo | 0.23 (0.01) | 0.24 (0.01) | -0.01 (-0.03, 0.02; 0.697) | -0.01 (-0.04, 0.02; 0.484) |
| QALYs from 12mo to 24mo | 0.73 (0.03) | 0.75 (0.03) | -0.02 (-0.10 , 0.06; 0.612) | -0.03 (-0.10 , 0.05; 0.449) |
| TOTAL QALYs over 24mo | 1.36 (0.06) | 1.39 (0.04) | -0.03 (-0.18, 0.12; 0.713) | -0.05 (-0.17 , 0.07; 0.386) |
| TOTAL QALYs over 24mo (time-discounted) | 1.34 (0.06) | 1.36 (0.04) | -0.03 (-0.17 , 0.12; 0.715) | -0.05 (-0.17 , 0.07; 0.385) |

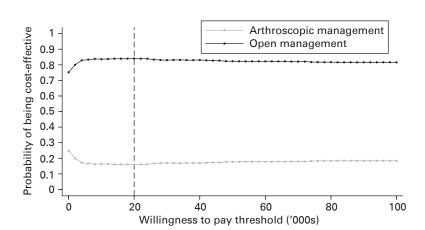
Table 6: Incremental analysis, per protocol analysis using imputed data

| | Total costs (time-discounted) ¹ | | | Total quality-adjusted life years over 24 months (time-discounted) ¹ | | | ICER Probability that arthroscopic repair is: [quadrant] ² | | | | | |
|---------------------------|--|---------------|---|---|----------------|---|---|-------------------|-------------|----------|-----------|--|
| Adjustment for covariates | Arthroscopic | Open | Difference (adjusted for covariates) | Arthroscopic | Open | Difference (adjusted for covariates) | | More effective | Less costly | Dominant | Dominated | Cost- effective at £20 000 per QALY gained |
| Unadjusted | 3582 (223) | 3360 (171) | 222 (-328 to 773; 0.426) | 1.34 (0.06) | 1.36 (0.04) | -0.03 (-0.17 to 0.12; 0.715) | Dominated (-8272; NW) | 36.5% | 19.2% | 9.9% | 55.1% | 30.0% |
| Adjusted ³ | 3582 (223) | 3360 (171) | 207 (-341 to 754; 0.456) | 1.34 (0.06) | 1.36 (0.04) | -0.06 (-0.17 to 0.06; 0.319) | Dominated (-3628; NW) | 21.2% | 24.3% | 8.5% | 63.0% | 18.8% |

¹ Uncertainty around costs and effects was calculated parametrically; ² ICER=incremental cost per quality-adjusted life year gained. Uncertainty around the ICER was estimated using 1000 bootstrap replicates of final merged data set after multiple imputation; ³ Covariates: EQ-5D at baseline (for QALY outcomes only), Age, Tear size, Centre







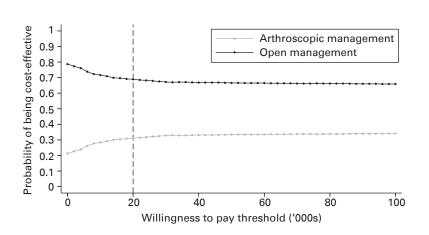


Fig. ab

Fig. bb