Title: Preserved quality of life in octogenarians at early, mid and late follow-up intervals irrespective of cardiac procedure.

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Glossary of abbreviations

24 TAVI - Transcatheter aortic valve implantation

25 SF-12v2 - Medical Outcomes Study Short Form 12 Health Survey version 2

26 CABG - Coronary artery bypass surgery

27 SD – Standard deviation

28 SPSS – Statistical package for the social sciences

29 RRT – Renal replacement therapy

30 QOL – Quality of Life

31 UK – United Kingdom

32 CPB time - cardiopulmonary bypass time

33 PVD - Peripheral vascular disease

34 LV - left ventricular function

35 CICU - cardiac intensive care unit

36 FU - follow-up period

37 LOS – length of stay
Abstract

Objective: Cardiac surgery has become established in octogenarians over the last decade. This study assessed the quality of life and survival in patients undergoing various cardiac procedures at various time intervals post-op.

Method: Patients over 80 years old at the time of their cardiac procedure were initially included (n=427). Patients were grouped according to the time interval from their operations namely as within 3 years post-op (Group A), 3 to 5 years post-op (Group B), and over 5 years post-op (Group C). Patients who were at least 2-years post-op and who were still alive were sent the SF12v2 quality of life questionnaire (n=308).

Results: There were no significant differences in the pre-op characteristics between the groups including type of surgery and logistic Euroscore. There were also no significant differences in the immediate post-operative phase in the complications rates except for renal replacement therapy (p<0.01). At follow-up, a further 20 patients had died and for those still alive 87% (61/70), 86% (86/100) and 74% (87/118) patients returned questionnaire for each group respectively. There was no significant differences in mental scores (p=0.3) and physical scores (p=0.07) between the groups at the various time intervals. This was irrespective of the type of surgery carried out on multi-variate analysis. Moreover, most octogenarians who had cardiac surgery had equivalent or better quality of life than expected when compared to the general population of the same age and sex.

Conclusion: Quality of life in octogenarians undergoing cardiac surgery is preserved, irrespective of the time interval from and the type of procedure.

Word Count Abstract: 250
Octogenarians enjoy a good quality of life, both physical and mental performance, irrespective of the time interval after surgery and the type of cardiac surgery that they have undergone. Based on this data, any type of cardiac surgery should still be an option in this age group.
Approximately 18% of the United Kingdom population is 80 years of age and older with an average life expectancy of 8 years [1]. As the proportion of octogenarians increases so will the demand for cardiac surgery. Moreover, the availability of percutaneous valve therapy (Transcatheter aortic valve implantation - TAVI) has led to a doubling in the number of octogenarians operated within our services. Although several publications have documented operative results in octogenarians for coronary artery surgery and aortic valve surgery, there is limited data about long term outcomes and quality of life in this group including those undergoing complex cardiac surgery [2,3,4,5]. Overall, there seems to be a consensus that cardiac surgery in the over 80 years-old group is associated with good early and mid-term outcomes as well as a satisfactory quality of life. This study assessed whether quality of life is preserved at various time intervals post cardiac surgery and the impact on the type of surgery at follow-up in this age group.

Materials and Methods

Patients who underwent cardiac surgery at our institution during the period of 2005 to 2012 and who were over 80 years of age at the time of their cardiac procedure were initially included (n=427). During the period 2005-2012, a total of 7397 patients underwent cardiac surgery in our Unit with the octogenarians representing around 4% of the group in 2005 increasing to 7.8% in 2012.

Patients were grouped according to the time interval from their operations as within 3 years post-op (Group A - early), 3 to 5 years post-op (Group B – mid-term), and over 5 years post-op (Group C - late). Patients who were at least 2-years post-op and who were still alive were sent the Medical Outcomes Study Short Form 12 Health Survey version 2 (SF-12v2, QualityMetric Health Outcomes Scoring Software 4.5, Optum, Lincoln, USA) quality of life questionnaire (n=308) [6]. Presumed consent was assumed if patient returned the questionnaire. The initial post-op data was prospectively collected on our database (PATS, Dendrite Clinical Systems, Ltd, Oxford, UK) and patient’s death was confirmed by contacting their general practitioner. The types of cardiac surgery were isolated coronary artery bypass surgery (CABG), isolated valve surgery (aortic or mitral valve surgery) or complex cardiac procedures (combined CABG & valve surgery, multiple valve surgeries, surgery on the aorta and aortic dissection surgery). This study was agreed as a service evaluation within the Hospital’s Research and Development Department following its peer-review process. Funding was provided by the local Cardiothoracic Services charitable fund.
Statistics

Categorical data are expressed as percentage and differences between the two groups assessed using the chi square ($X^2$) test of independence. Continuous variables are expressed as mean (SD) or median (range) for Gaussian and skewed distributed data respectively. Likewise group comparison was carried out using the t-test or non-parametric test accordingly. The tests were considered significant at $p \leq 0.05$. SPSS version 16.0 (SPSS Inc. Chicago IL) was used for statistical analysis. Survival was assessed using the Kaplan-Meier survival curve. Binary logistic regression analysis was performed to assess the factors (type of procedure, time interval from surgery, age, gender, diabetes, duration of cardiopulmonary bypass, post-operative complications - infections & need for renal replacement therapy, blood transfusion within 24 hours of surgery, duration of in-hospital stay and logistic EuroScore) predicting the probability or odds of patients below the median value for the physical and mental scores as the dichotomous dependent variable. The model was refined using backward elimination.

Results

There were 76 patients, 109 patients and 123 patients in Groups A, B and C respectively. There were no significant differences in the pre-op characteristics between the groups including age, gender, priority of surgery, left ventricular ejection fraction, type of surgery and logistic Euroscore (Table 1). There were also no significant differences in the immediate post-operative phase in the complications rates such as infection, neurological problem, airway support, ICU re-admission and in-hospital mortality, except for the need of renal replacement therapy ($p<0.01$) (Table 2). The latter may represent in a shift in our approach with the institution of renal replacement therapy (RRT) in the post-op cardiac setting over time (RRT is now instituted much earlier than it was in 2005). Overall, the post-op rate of stroke at discharge was low at 0.7% (2 patients).

The 30-day mortality was 8.8% for isolated CABG, 17.6% for isolated valve (aortic or mitral) procedures and 25.3% for those patients who underwent complex operations.

At follow-up, a further 20 patients had died and for those still alive 87% (61/70), 86% (86/100) and 74% (87/118) patients returned the questionnaire for each group respectively. Overall, when compared to the general elderly population (matched age and gender), the octogenarians study group performed better in their mental score in 54% of patients and the physical score were as good as or better.
better than their matched age and sex population in 65% (Figure 1). There was no significant
differences in the mental scores (p=0.3) and the physical scores (p=0.07) between the groups at the
various time intervals (Figure 2). This was irrespective of the type of surgery carried out when
assessed on multi-variate analysis.

However, the type of surgery did impact on survival and is illustrated in Figure 3 (p< 0.01).
The numbers of patients at-risk as well as the percentage survival (95% confidence interval) for each
procedure group is detailed in the Legend for Figure 3.

Discussion

Cardiac surgery in octogenarians accounts for up to 10% of our yearly surgical activity, in this
current era. This ever increasing proportion of octogenarians undergoing cardiac surgery has been
partly due to the availability of the TAVI program within our Centre as the latter has led to more
octogenarians being referred for surgery. There are some limited reports in the literature regarding
long-term survival and quality of life [7]. In this study, Ghanta et al concluded that cardiac surgery in
this age group can be performed with low operative mortality, excellent long-term survival (actuarial
survival of 53% and 27% at 5 and 10-year respectively) and better quality of life when compared to
the general elderly population [7]. However, they only had 114 replies for their QOL questionnaires. In
an earlier publication, the same group confirmed that the above outcomes can be achieved even in
the non-elective setting [5].

Good quality of life using a different type of quality of life questionnaire (modified Seattle
Angina Questionnaire) at medium term follow-up (mean 890 days) was also reported by Huber et al in
120 patients undergoing cardiac surgery in Switzerland [8].

In a review of the literature comparing cardiac surgery in the octogenarian group to their
younger counterparts, Weideman et al reported that as expected operative mortality was higher in the
elderly group (9.1% v/s 3.4%) [9]. Interestingly from this report, mortality was highest when patients
underwent combined mitral valve surgery (mortality of up to 30%).

Results for complex cardiac procedures in octogenarians have been published and included
combined cardiac procedures and procedures on the aorta [7,10,11,12] with all groups reporting
reasonable and acceptable post-operative outcomes. This is also confirmed in the current study with
30-day mortality being 8.8% for isolated CABG, 17.6% for isolated valve (aortic or mitral) procedures and 25.3% for those patients who underwent complex operations.

Any discussion regarding surgery in the octogenarian group will be incomplete if TAVI is not included. Although TAVI has provided good early outcome and quality of life, it has its own set of risks including in-hospital mortality (5%), need for permanent pacemaker (10-15%), vascular access injury (10%) and paravalvular leak (10% more than mild) [13,14,15]. Cardiac surgery, on the other hand, has a different set of complications but is also associated with a longer post-operative recovery. However, the longer-term outcome of TAVI is still unknown and the durability of these valves still remains to be confirmed.

This study also confirmed that octogenarians who had cardiac surgery and recovered well thereafter, enjoy a better quality of life than their contemporaries from the general age and gender matched population. This is vital information for health care providers in their decision making process in terms of funding or reimbursement for this age group.

Finally, this data showed that the octogenarians benefit from cardiac surgery and had good quality of life even in the longer term and these benefits spread across the whole gamut of cardiac surgical procedures. This was also reported-on in terms of early and mid-term benefits in the literature by various authors [5,7,10,11,12]. Thus octogenarians should be considered for any type of cardiac surgical procedures provided the surgical assessment of risks is deemed acceptable.

Conclusion

Quality of life in octogenarians is preserved irrespective of the time interval after surgery and irrespective of the type of surgery. Based on this evidence, surgery, even complex cardiac procedures, still provides a good option especially in the long-term in this era of TAVI procedures.

Limitations

This study is limited by the fact that it was a questionnaire design and voluntary replies from octogenarians. Overall 81% of patients returned the questionnaire. The reasons for not returning the questionnaire included a change of address, patient unwilling to participate and possibly some patients being unwell and unable to complete the questionnaire.
Acknowledgement

We sincerely acknowledge the help and assistance of all the anaesthetic, surgical, cardiac intensive care and ward staff as well as the paramedical staff at the Heart and Lung Centre, Wolverhampton, UK.

References

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6. Ware J, Kosinski M, Turner-Bowker D, Gandek B. How to score version 2 of the SF-12 Health Survey. Lincoln, RI: QualityMetric Inc;2005


Table 1: pre- & peri-op characteristics of patients for the groups

<table>
<thead>
<tr>
<th></th>
<th>Group A (&lt;3 yr post-op)</th>
<th>Group B (3 to 5 yr)</th>
<th>Group C (&gt;5 yr post-op)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>76</td>
<td>109</td>
<td>123</td>
<td></td>
</tr>
<tr>
<td>Age*, years</td>
<td>81.9 (1.8)</td>
<td>82.1 (1.9)</td>
<td>81.5 (1.4)</td>
<td>0.1</td>
</tr>
<tr>
<td>CPB time*, minutes</td>
<td>99 (49)</td>
<td>101 (60)</td>
<td>97 (43)</td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td>Group A (&lt;3 yr post-op)</td>
<td>Group B (3 to 5 yr)</td>
<td>Group C (&gt;5 yr post-op)</td>
<td>p-Value</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------------------------</td>
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<td>-------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>N</td>
<td>76</td>
<td>109</td>
<td>123</td>
<td></td>
</tr>
<tr>
<td>Airway support (%n)</td>
<td>11%, 8</td>
<td>8%, 9</td>
<td>11%, 13</td>
<td>0.8</td>
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<tr>
<td>Chest infection (%n)</td>
<td>14%, 10</td>
<td>10%, 11</td>
<td>10%, 12</td>
<td>0.7</td>
</tr>
</tbody>
</table>

*denotes mean (SD)

CPB time: cardiopulmonary bypass time

PVD: Peripheral vascular disease

LV: left ventricular function

Table 2: Post-operative data
<table>
<thead>
<tr>
<th>Any infection (%,n)</th>
<th>27%, 20</th>
<th>16%, 17</th>
<th>22%, 26</th>
<th>0.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confusion (%,n)</td>
<td>10%, 6</td>
<td>11%, 12</td>
<td>7%, 8</td>
<td>0.5</td>
</tr>
<tr>
<td>RRT (%,n)</td>
<td>18%, 14</td>
<td>7%, 8</td>
<td>6%, 7</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CICU re-admission</td>
<td>2.6%, 2</td>
<td>5.5%, 6</td>
<td>4.1%, 5</td>
<td>0.6</td>
</tr>
<tr>
<td>Mortality at FU (%,n)</td>
<td>7.9%, 6</td>
<td>8.3%, 9</td>
<td>4.1%, 5</td>
<td>0.4</td>
</tr>
<tr>
<td>Post-op LOS**, days</td>
<td>8 (4.48)</td>
<td>7 (4,100)</td>
<td>8 (4.44)</td>
<td>0.1</td>
</tr>
</tbody>
</table>

** denotes median (range)

Airway support includes need for CPAP ventilation, re-intubation and/or tracheostomy

RRT: renal replacement therapy

CICU: cardiac intensive care unit

Mortality at FU: mortality during follow-up period

LOS: length of stay

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**Figure Legends**

**Figure 1**

Percentage of sample whose (a) Physical Scores and (b) Mental Scores (SF-12) are above, at or below the General Population Norm (age and gender matched)

(a) Physical Scores and (b) Mental Scores
Figure 2: Mean (95% CI) for the (a) Physical Scores and (b) Mental scores for the various time intervals

<table>
<thead>
<tr>
<th>Time interval</th>
<th>&lt;3 years post-op</th>
<th>3 to 5 years post-op</th>
<th>&gt;5 years post-op</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>61</td>
<td>86</td>
<td>87</td>
</tr>
<tr>
<td>Physical Score</td>
<td>44.7 (42.5, 46.9)</td>
<td>41.6 (39.8, 43.4)</td>
<td>43.8 (42.1, 45.5)</td>
</tr>
<tr>
<td>Mental Score</td>
<td>52.3 (50.1, 54.5)</td>
<td>52.5 (50.9, 54.1)</td>
<td>53.7 (52.1, 55.3)</td>
</tr>
</tbody>
</table>

Figure 3: Kaplan-Meier survival curve for the various types of surgery (n=427)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Time (months)</th>
<th>0</th>
<th>20</th>
<th>40</th>
<th>60</th>
<th>80</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG</td>
<td>n</td>
<td>171</td>
<td>151</td>
<td>131</td>
<td>111</td>
<td>91</td>
<td>71</td>
</tr>
<tr>
<td>Survival (95% CI)%</td>
<td></td>
<td>95 (92,98)</td>
<td>94 (90,98)</td>
<td>93 (89,97)</td>
<td>92 (88,96)</td>
<td>91 (86,96)</td>
<td></td>
</tr>
<tr>
<td>Isolated Valve</td>
<td>n</td>
<td>74</td>
<td>54</td>
<td>34</td>
<td>14</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>Survival (95% CI)%</td>
<td></td>
<td>91 (84,98)</td>
<td>86 (77,95)</td>
<td>82 (71,93)</td>
<td>52 (22,82)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Complex operation</td>
<td>n</td>
<td>182</td>
<td>162</td>
<td>142</td>
<td>122</td>
<td>102</td>
<td>82</td>
</tr>
<tr>
<td>Survival (95% CI)%</td>
<td></td>
<td>89 (84,95)</td>
<td>80 (74,86)</td>
<td>80 (74,86)</td>
<td>78 (72,84)</td>
<td>76 (69,82)</td>
<td></td>
</tr>
</tbody>
</table>