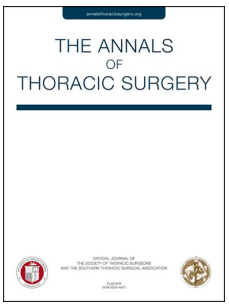

Outcomes and quality of life after Ross reintervention: would you make the same choice again?

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Outcomes and quality of life after Ross reintervention: would you make the same choice again?

Running Head: Psychological burden of reoperations after Ross

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Abstract

Background: The Ross procedure was introduced as a long term if not definitive solution for aortic pathology. However, the rate of reoperation is not negligible.

Methods: Single center prospective study assessing the general outcome of Ross reoperation and patients perceived quality of life compared with two control groups (Ross non reoperation and mechanical aortic valve replacement). Patient's preference, regarding the choice between mechanical aortic valve and Ross procedure, was investigated in a subgroup who could theoretically have been directed to either of the two procedures.

Results: Between 2005 and 2017, 64 consecutive patients underwent reoperation after Ross. Median age was 31 years. Median freedom from reoperation after Ross procedure was 136 months. Forty-nine patients required autograft reoperation and 25 had homograft failure. No in-hospital mortality was recorded. Mean follow-up was 77 months(range 6-164). Short Form Health Survey (SF-36) questionnaire was administered, to assess the quality of life. Ross reoperation group showed a lower score involving psychological concerns compared to other groups.

In reoperated patients group, 52 had adequate aortic annulus dimensions to receive a prosthetic valve instead of a Ross procedure. When asked if they would make the same choice, only 31% confirmed the preference.

Conclusions: Reoperations after Ross procedure have low mortality and morbidity. Long-term follow-up showed a high quality of life, even after reoperations. However, due to psychological concerns following redo surgery, when choosing a Ross procedure, it is our duty to thoroughly explain to patients that in case of reoperations a high level of disillusion is predictable.

The Ross procedure was introduced in 1967 as a long-term if not definitive solution for aortic valve pathology [1]. Today the tendency is to perform this procedure mainly in pediatric population and in women of childbearing age [2]. The percentage of reoperations after Ross is not negligible, varying from 20 to 70% [2-6]; additionally, they carry the burden of high complexity. In this context, the choice of Ross operation requires a delicate interview with patients to exactly explain what may happen in the future. However, many studies show no significant differences in terms of long-term survival and freedom from reoperations between Ross procedure and mechanical prostheses implantation [3-6] and a recent propensity-score matched study demonstrates that the Ross procedure is associated with even better long-term survival in suitable patients, compared with mechanical AVR (mAVR) [7]. The primary end-point of the study is to assess the general outcome after Ross re-operations. Secondary endpoints include the assessment of quality of life (QoL) by SF-36 and evaluation of post-procedural satisfaction after Ross procedure, in a subgroup of patients, who could have theoretically been treated with conventional aortic valve replacement, compared with two control groups.

Patients and Methods

We included 64 patients referred at our institution for reoperation after Ross procedure, between 2005 and 2017. Institutional Database was used for retrospective data collection; follow-up data were retrieved from clinical records and by telephone contact with the patient. Local Ethics Committee approved the study (19/int/2019) and all the patients signed a written consent.

Quality of life questionnaire

To assess quality of life a Short Form(36)Health Survey(SF-36) questionnaire was administered to all patients at least 6 months after surgery (Fig 1). The SF- 36 is a questionnaire developed to measure generic health concepts relevant across age, disease and treatment groups. It provides a comprehensive, psychometrically sound and efficient way to measure health from the patient's point of view, by scoring standardized responses to standardized questions.

The SF-36 has 36-items that measure eight multi-item dimensions of health: physical functioning (10 items), role limitations due to physical problems (four items), role limitations due to emotional problems (three items), social functioning (two items), mental health (five items), general health perceptions (five items), energy and vitality (four items), and bodily pain (two items).

In addition, we enclosed 3 specific questions related to the Ross procedure as follows: i)After Ross intervention did you really feel free to do what you wanted, without limitations? ii)Did the reoperation have a significant emotional impact for you? iii)Can you tolerate the anticoagulant therapy well?.

Furthermore, in the subgroup of patients without contraindication to anticoagulation therapy and with aortic annulus dimensions adequate to receive a mechanical prosthesis (i.e. aortic diameter > 18 mm, age < age <40 years old and EF > 50%), due to the possibility of both surgical alternatives, we asked if they would choose the Ross procedure again.

We compared the SF-36 questionnaire results in our series with two control groups of patients operated in our center in the same time period (February 2005- December 2017). The first control group, Ross non reoperation (RnR), included patients who underwent Ross procedure, and did not need re-operations during follow up. Sixty-three patients were identified, with mean age of 16±9 years, 37 males and 26 females. All patients answered the questionnaire.

The second control group (mAVR) consisted of 53 patients (mean age 26±9 years) who underwent isolated aortic valve replacement with mechanical prosthesis. Inclusion criteria in this group were age < 40 years, 41 males and 12 females, ejection fraction of the left ventricle >50%. One patient did not reply to the questionnaire.

Statistical analysis

All pre-, intra-, and postoperative data were collected. Continuous data were analyzed using the unpaired Student's t test, and categorical data were analyzed using the $\chi 2$ test or Fisher exact test. Values were expressed as mean±standard deviation. For the comparison between groups a P value <0.05 was considered significant. The responses to the SF 36 questionnaire were checked with the recommended tests of reliability and validity [8, 9].

We examined the internal consistency by item to own dimension correlations calculated after correction for overlap using Cronbach's a score. Reliability coefficients for each dimension were calculated by two-way analysis of variance [10]. Non-parametric versions of these tests were used to avoid any distributional assumption. Considerable evidence was found for the reliability of the scores obtained in each of the 8 domains of the SF-36 test (Cronbach's a score greater than 0.85, reliability coefficient greater than 0.75 for all dimension except social functioning (a=0-7, reliability=0 72). The statistical analysis was performed using the SPSS statistical software package (Version 11.5 for Windows, SPSS Inc.; Chicago, Ill).

Results

Pre-operative characteristics and demographic

Sixty-four patients underwent Ross procedure between February 1994 and October 2004 at a mean age of 19.6±9.4 years. Thirty-nine patients (61%) were operated in other institutions. The main indication for Ross intervention was aortic stenosis (45 patients); 36 had a bicuspid aortic valve (BAV). Details of operative data at time of the Ross procedure are shown in Table 1. Two patients were previously re-operated in another institution before coming to our attention: one patient underwent aortic valve replacement for aortic valve insufficiency and one patient had homograft replacement with biological conduit for severe stenosis. Percutaneous pulmonary valve implantation (PPVI) was performed in four patients after failure of the previously implanted right ventricular conduit. Mean freedom from reoperation after Ross procedure was 136±64 months and the mean age at reoperation was 30.5±10 years.

Operative procedures and outcomes

Overall, 96 procedures were performed in our cohort, with 49 patients requiring autograft reoperation. Main indication was aortic regurgitation with or without aortic root/ascending aorta dilatation. Twenty-five patients received a surgical procedure for right ventricular outflow tract (RVOT) failure: pulmonary valve conduit implantation in 14 and bioprosthesis in 11 patients, respectively. Ten patients needed a combined left and right outflow tract procedure. Twenty-two patients required other concomitant surgeries. Among 36 patients with native bicuspid aortic valve (BAV), 34 required reoperation for autograft failure with aortic

root dilation and cusp prolapse. Valve regurgitation and root aneurysm were present in 29 patients, isolated regurgitation in five patients. All data are reported in Table 2.

In BAV group, 30 patients underwent reoperation on the left side, four patients on both left and right side and two patients only on the right side. In the remaining 28 patients with native tricuspid aortic valve (TAV), ten received a reoperation on the left side; five on both right and left side, and 13 for right outflow tract failure. Although it is necessary to be cautious about this, considering our patient selection bias, we noticed that in our series BAV group had significantly more procedures on the left side, than on the right-side (N=29 vs N=2), compared to the TAV group (N=10 vs N=13), $p<0.001$. Data shown in Table 3.

The homograft in the right outflow tract was replaced in 25 patients. Indications were severe stenosis (16 patients), severe pulmonary valve regurgitation with homograft aneurysm (3 patients) and infective endocarditis (4 patients). In two patients, we replaced a calcified but otherwise well-functioning pulmonary homograft, due to the surgical damage occurred during the dissection of the dense adhesions with the autograft. Four patients underwent percutaneous pulmonary valve implantation inside the homograft.

Cardiopulmonary by-pass and cross clamp mean time were 142±53 and 97 ± 44 minutes, respectively. Mean intensive care unit stay was 2.7±4.3 days (range 1-33 days). There was no in-hospital mortality. The most frequent complication was complete AV block requiring pacemaker implantation (6.2%). Mean hospital stay was 12.4±8 days (range 5-41 days). Postoperative complications are shown in Table 2.

Follow-up results

Mean follow up was 77±41 months and 100% complete. There was one late death not cardiac related, one infective endocarditis medically treated and no major cerebrovascular events. One patient had a second re-intervention after Ross reoperation for aortic valve regurgitation following bacterial endocarditis. This patient underwent pulmonary homograft replacement with porcine bioprosthesis 84 months after the first Ross procedure. Seventy-six months later was diagnosed with bacterial endocarditis on the autograft, which

needed replacement with mechanical prosthesis. Three patients underwent percutaneous pulmonary valve implantation.

Quality of life questionnaire (SF-36 short form) and specific inquiries regarding QoL were completed by 63 patients of our Ross reoperation cohort. Results of SF-36 health survey are shown in Table 4.

Overall, we found high scores in almost all eight multi-item dimensions of health in all three groups (RR, RnR and mAVR). In RR group the emotional and mental health score was significantly lower compared to both control groups. In Table 5 are depicted the answers to specific inquiries. Thirty-eight patients (59%) after Ross intervention did not feel comfortable doing sports and fifty-three (83%) reported a strong psychological impact of reoperation on their lives. Anticoagulation therapy was well-tolerated in 93% of patients.

A subgroup of 52 patients, in RR group, had the aortic annulus dimensions adequate to receive a satisfactory size mechanical prosthesis (mean diameter 22.9±3.4 mm, range 18-26 mm) at the time of the first Ross procedure. Mean age in this subgroup was 22±9.4 years (range 10-48 years) and mean freedom from reoperation after Ross procedure was 137.4±64 months (range 28-271 months). However, the results of the interview highlighted that only 31% would choose again the Ross procedure.

Comment

Our study showed that re-intervention after the Ross procedure are complex, often involving both right and left sided surgeries, thus determining significant morbidity. The long-term results of the Ross procedure are not consistent in all reports [11]. David and Sievers [12,13], for example, presented a cumulative incidence of Ross-related reoperation at 20 years of less than 20%. In contrast, Martin [14] reported, among 310 patients undergone Ross procedure, a 20 years freedom from reoperation of 70.1% [15]. Our experience demonstrates that the need of neo-aortic reintervention is 19% at 12 years for adult patients and 20% at 10 years in pediatric population [16,17].

Several studies highlighted how native aortic stenosis has greater freedom from autograft re-intervention [18,19], while aortic regurgitation and geometric mismatch between the aortic

and the pulmonary valve diameter are associated with poorer outcomes [18]. When considering the Ross procedure, complications on the RVOT must be addressed, whose incidence depend upon the patient's age and the type and size of the implanted conduit [20-23]. Due to these and other factors, re-operation after Ross procedure require high surgical expertise and carries a non-negligible risk [24].

In our study, the first end-point was to analyze the outcomes of reoperations after Ross procedure. Our series do not permit to assess the frequency of reoperation, because many of these patients had their Ross operation elsewhere, nor was that the aim of the present study. Our results demonstrate that re-interventions are complex, because surgical correction is required to address multiple associated cardiac anomalies and the postoperative period is often not straightforward. In this perspective, and in order to find a more definitive surgical solution to avoid multiple reoperations, a mechanical aortic valve replacement was our preferred choice during neoaortic reoperations, and only in one case we performed an aortic valve sparing technique.

In patients listed to Ross operation, preoperative bicuspid aortic valve morphology represents the most controversial risk factor for autograft dysfunction. The latest guidelines for aortic valve and ascending aorta published by Society of Thoracic Surgeons indicate that the Ross procedure is not recommended for patients with BAV. However, the level of evidence for this recommendation is low [25].

In some studies, in fact, histologic abnormalities of the pulmonary artery in patients with BAV and association between BAV anatomy and pulmonary autograft dysfunction after Ross procedure have been described [26-28]. However, only few studies have illustrated an impact of BAV morphology on autograft durability. In contrast, some studies have not indicated BAV as a predictor of autograft dysfunction [26,29].

In our series 36 patients (56%) had BAV and the remaining 28 TAV (44%). We could not identify any significant difference between groups in terms of median age at the time of Ross procedure and time elapsed between the first Ross operation and Ross re-operation. On the contrary, even if we cannot generalize for the selection bias of patients (only reoperated), we found a significant statistical difference on the side of the re-intervention (left sided or right sided intervention). In fact, native BAV patients showed a higher reoperation rate on the left side.

One of the heaviest criticisms of Ross procedure is that it transforms a single-valve problem in a potentially "two-valve disease". In our series, indeed, 25 patients required surgical treatment of RVOT and three patients underwent PPVI during follow up. In this group of patients, the PPVI had a good immediate and short-term result. Without homograft calcification, we preferred to implant a stented biological prosthesis. We used this technique, instead of homograft replacement, because it minimizes mediastinal dissection, bleeding and surgical times, providing a durable support for subsequent percutaneous procedures.

In 15% patients was necessary to perform associated surgical procedures related to the primary Ross operation.

Coronary ostia lesions may probably be attributed to a less than perfect coronary re-implantation; and tricuspid regurgitation is probably due to right ventricle dilation secondary to homograft failure.

In our series, despite the absence of early mortality, morbidity was probably considerable if compared with a more straightforward reoperation for re-replacement of a prosthesis valve, but the incidence of early complications are comparable with other series of ross reoperation [22, 24].

Observed incidence of late mortality is very low (N=1, 1.5%) and none of those patients who received mechanical AVR had hemorrhagic or thromboembolic events. Reoperations after Ross surgery often involve double or triple procedures. In our series, in fact, 64 patients had a total of 98 surgical procedures. Additionally, four patients received a second redo cardiac surgery, highlighting the incremental risk of surgical re-operations following Ross procedure even if our low in-hospital mortality rate.

Secondary end point was to evaluate the quality of life of these patients. Although mortality and morbidity data provide an important piece of information about the disease, it is impossible to separate the disease from patient's personal and social context. The use of QoL measures in the clinical practice ensures that treatment focuses on the patient, rather than on the disease.

To better understand the meaning of our investigation we compared the QoL between three groups: RR, RnR and mAVR. Our data show that there are not significant differences in the quality of life among the three

groups, except for a significant reduction in the measure of emotional and mental health in the RR group compared to the two control groups. This last result is probably due to the psychological impact that these patients have to face after the re-operation and likely also to the prospective of other future surgeries procedures. The Ross non reoperation group had the highest score in the SF-36, results consistent to those of Zacek et al [30]. Regarding patient's lifestyle, only 41% of the Ross reoperation group performed physical activity without fear and only 59%, despite their good clinical conditions, did not have confidence in playing sports. Most of patients (83%) felt difficult to accept the idea of undergoing a new operation, while 95% of them did not report any problem or adverse event following anticoagulation therapy.

In cardiac surgery, when facing different options, surgeons often meditate on the proper choice. Sometimes, if possible, we would go back and change our decision, and the same feeling may apply to patients. For this reason, we asked if the subgroup of Ross re-operated patients, with annulus dimensions adequate to receive a mechanical prosthesis, would confirm the same choice again. Even if the long-term outcome of Ross procedure in this subgroup of patients was "surgically" good (almost ten year freedom from reoperation and an high QoL score), the result of "patient's point of view" was surprising because only 36 (69%) replied that they would not choose again the Ross operation. The main reason, indeed, was that most of patients expected a longer freedom from reoperation after Ross and did not understand correctly what would happen in their future. This is a crucial results, because not always patient's expectations correspond to what physicians consider a good clinical result.

Another important issue is the anticoagulation therapy in terms of management and complications. The propensity-adjusted analysis by Alsoufi et al., highlighted comparable outcomes in short- and long-term follow-up between Ross procedure and mechanical aortic valve replacement [31]. Mockhles and associates found that there was no survival advantage for the Ross procedure over the use of mechanical valves, providing a good compliance to anticoagulation regimen [32]. Therefore, when choosing Ross procedure instead of mechanical valve replacement, both the physician and the patient, should consider the predictable adherence

to an optimal anticoagulation therapy. Maybe, in the future, advances in anticoagulation drugs may shift the balance more in favor of mechanical prosthesis [33].

Limitations

In consideration of our role of tertiary center with some referral hospital, our data probably suffer from a natural selection bias and so no general considerations should be made. The major constraint of our study is the relatively small population, which does not permit a correct evaluation of the overall risk of reoperation after Ross. However, the aims of our study were different from defining the incidence of reoperation.

Conclusion

Reoperations in Ross patients are relatively frequent and, despite complexity of the surgical procedure, the results are excellent in terms of survival. Quality of life is good after reoperation and is not significantly affected by the need of anticoagulation for mechanical prosthesis.

The majority of patients who underwent reoperation after Ross, however, would not choose this procedure again, if they would have considered the higher risk of reoperation. Thus, it is essential, when proposing Ross operation, to extensively explain the expected outcomes and risk of reoperation compared to other surgical alternatives.

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Table 1. Patient's details at Ross operation

Variables	**(N=64)**
Mean age (range)	19.4±9.4 (2-48)
Aortic valve stenosis	45(70)
Aortic valve insufficiency	6(10)
Mixed aortic valve lesion	13(20)
Bicuspid aortic valve	36(56)
Stenosis	19
Insufficiency	5
Mixed	12
Previous valvuloplasty	14(21)
Previous surgical procedure (N=32)	
- Valvulotomy	9(28)
- Decoarctation	7(22)
- Subvalvular stenosis resection	6(19)
- Aortic valve repair	6(19)
- VSD closure	3(9)
- Aortic arch repair	1(3)
Mini root technique	53(82.8)
Subcoronary	8(12.5)
Inclusion	3(4.6)

Data are mean±standard deviation) or number (%)
VSD=ventricular septal defect.

Table 2. Intraoperative variables at redo operations and early complications.

Procedures	**(N=64)**
Bentall operation, n (%)	30(29)
+ PCI, n (%)	7(10.9)
+ TVRep, n (%)	3(4.6)
+ MVR, FA ablation, n (%)	2(3.1)
+ CABG, n (5%)	2(3.1)
+ MVR, n (%)	2(3.1)
AVR, n (%)	13(20.3)
Biological, n (%)	1(1.5)
Mechanical, n (%)	12(18.7)
+ PVI, n (%)	1(1.5)
+ PCI, n (%)	1(1.5)
+ CABG, n (%)	3(4.6)
Wheat operation, n (%)	5(7.8)
+ CABG, MVR, FA ablation, n (%)	1(1.5)
+ PCI, MVR, FA ablation, n (%)	1(1.5)
Pulmonary conduit implantation, n (%)	7(10.9)
Pulmonary valve implantation, n (%)	8(12.5)
+ TVRep, n (%)	2(3.1)
David + MVR, n (%)	1(1.5)
Variables	
CPB time, mean, min	141.6±53
Cross clamp time, mean, min	97±44
Complications	**(N=64)**
In-hospital mortality	0(0)
Reoperation for bleeding	3(4.6)
Permanent pacemaker implantation	4(6.2)
Acute kidney injury	1(1.5)
Sternal wound infection	2(3)
Miocardial infarction	1(1.5)
Left cerebellar ischemia	1(1.5)
ARDS	1(1.5)

Data are mean (standard deviation) or number (%)

PCI, pulmonary conduit implantation; TVRep, tricuspid valve repair; MVR, mitral valve replacement; FA, atrial fibrillation; AVR, aortic valve replacement; PVI, pulmonary valve implantation; CABG, coronary artery bypass graft; ARDS, acute respiratory distress syndrome.

Table 3. Patient's details at reoperation

Variables	TAV(n=28)	BAV(n=36)	p
Mean age at Ross procedure, years,	17.2±9.3	21.9±9.2	0.80
Left heart reoperation,	10(35.7)	29(80.5)	
Right heart reoperation	13(46.4)	2(5.6)	<0.001
LR heart reoperation,	6(21.4)	4(11.1)	
Time from Ross procedure, months,	115.9±70.8	124.2±64.5	0.92
Mean age at Redo procedure, years,	28.2±9.9	32.2±9.6	0.80

Data are mean±standard deviation or number (%)
TAV=tricuspid aortic valve;BAV=bicuspid aortic valve.

Table 4. Patient's details at reoperation

Health parameters	**RR (n=64)**	**RnR (n=63)**	**mAVR (n=52)**
Physical functioning	84±16	86±17	85±17
Role limitation due to physical health	81±13	84±13	81±16
Role limitation due to emotional health	67±23	86±27	84±19
p value	***Ross>Ross reop***	***0.024***	
	AVR >Ross reop	***0.029***	
Energy and vitality	82±16	83±19	85±17
Mental health	76±29	85±19	84±21
p value	***Ross>Ross reop***	***0.042***	
	AVR >Ross reop	***0.047***	
Social functioning	85±27	85±23	84±21
Bodily pain	81±19	83±21	84±17
General health perception	88±14	87±14	87±16

RR: ross reoperation group
RnR: ross non reoperation group
mAVR: mechanical aortic valve replacement

Table 5. Questions at follow-up in Ross reoperation group

Questions	Yes(%)	No(%)
After Ross operation did you really feel free to do what you want without any limitation? (all patients)	41	59
Did the operation have a significant emotional impact on you? (all patients)	83	17
Can you bear the anticoagulant therapy well? (49 patients)	93	7
Would you make the same choice again? (52 patients)	31	69

Figure Legend

Fig. 1 Short Form (36) Health Survey (SF-36)

Label	SF-36 QUESTIONS
GH1	**1.** In general, would you say your health is:
HT	**2.** Compared to one year ago, how would you rate your health in general now?
	3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? Is so, how much?
PF01	**a.** Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports
PF02	**b.** Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
PF03	**c.** Lifting or carrying groceries
PF04	**d.** Climbing several flights of stairs
PF05	**e.** Climbing one flight of stairs
PF06	**f.** Bending, kneeling, or stooping
PF07	**g.** Walking more than a mile
PF08	**h.** Walking several blocks
PF09	**i.** Walking one block
PF10	**j.** Bathing or dressing yourself
	4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?
RP1	**a.** Cut down on the amount of time you spent on work or other activities
RP2	**b.** Accomplished less than you would like
RP3	**c.** Were limited in the kind of work or other activities.
RP4	**d.** Had difficulty performing the work or other activities (for example, it took extra effort)
	5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)
RE1	**a.** Cut down on the amount of time you spent on work or other activities
RE2	**b.** Accomplished less than you would like
RE3	**c.** Didn't do work or other activities as carefully as usual
SF1	
	6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
BP1	**7.** How much bodily pain have you had during the past 4 weeks?
BP2	
	8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
	9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks—
VT1	**a.** Did you feel full of pep?
MH1	**b.** Have you been a very nervous person?
MH2	**c.** Have you felt so down in the dumps that nothing could cheer you up?
MH3	**d.** Have you felt calm and peaceful?
VT2	**e.** Did you have a lot of energy?
MH4	**f.** Have you felt downhearted and blue?
VT3	**g.** Did you feel worn out?
MH5	**h.** Have you been a happy person?
VT4	**i.** Did you feel tired?
SF2	
	10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
	11. How TRUE or FALSE is each of the following statements for you?
GH2	**a.** I seem to get sick a little easier than other people
GH3	**b.** I am as healthy as anybody I know
GH4	**c.** I expect my health to get worse
GH5	**d.** My health is excellent

SF-36 RESPONSE CHOICES
1. Excellent, Very good, Good, Fair, Poor
2. Much better now than one year ago, Somewhat better now than one year ago, About the same as one year ago, Somewhat worse now than one year ago, Much worse now than one year ago
3. Yes, limited a lot; Yes, limited a little; No, not limited at all
4. & 5. Yes, No
6. Not at all, Slightly, Moderately, Quite a bit, Extremely
7. None, Very mild, Mild, Moderate, Severe, Very severe
8. Not at all, A little bit, Moderately, Quite a bit, Extremely
9. All of the time, Most of the time, A good bit of the time, Some of the time, A little of the time, None of the item
10. All of the time, Most of the time, Some of the time, A little of the time, None of the time
11. Definitely true, Mostly true, Don't know, Mostly false, Definitely false