Quality of Life After Percutaneous Coronary Intervention in No-Touch Saphenous Vein Grafts is Significantly Better Than in Conventional Vein Grafts

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ABSTRACT

Objective: To compare health-related quality of life (HRQoL) of patients primarily treated with a no-touch saphenous vein graft with that of patients who received a conventional graft.

Methods: The study included all individuals treated with a percutaneous coronary intervention (PCI) on a saphenous vein graft (SVG) between January 2006 and June 2020. The RAND-36 health survey was used to assess HRQoL. The Mann-Whitney U test was used to test differences in HRQoL between the two groups. Effect size was estimated via Cohen’s d. The average treatment effect between the groups was tested by propensity score matching (PSM).

Results: Of the 346 patients treated with a PCI in a stenosed or occluded SVG, 165 responded to RAND-36 (no-touch: n=48; conventional: n=117). Patients with a no-touch graft reported better mean values on seven of the eight health survey domains. Statistically significant differences were observed for four of the domains, all in favour of the no-touch group. The effect size estimates indicated a small difference for five domains, with the highest values (>0.40) seen for the general health and energy/fatigue domains. PSM confirmed a statistically significant difference for the physical functioning and general health domains.

Conclusion: At a mean follow-up of 5.4 years, patients who received a PCI in no-touch vein grafts showed significantly better HRQoL than those who received a PCI in conventional vein grafts.

Keywords: Coronary Artery Bypass. Quality of Life. Percutaneous Coronary Intervention. Saphenous Vein. Fatigue. Propensity Score.
INTRODUCTION

Health-related quality of life (HRQoL) has become an important outcome measure. Most medical treatments are now evaluated not only in terms of clinical/biomarker benefits but also in terms of HRQoL improvements. In 2011, Noyez et al. reviewed the literature regarding HRQoL studies after cardiac surgery. The review showed few HRQoL studies as well as methodological weaknesses such as limited follow-up times and limited sample sizes.

More studies have been published in the last decade, and almost all have used the SF-36 or the RAND-36 to measure HRQoL after cardiac surgery, in particular after coronary artery bypass grafting (CABG) operation. The RAND-36-item health survey 1.0 is a public domain and licence-free form equivalent to the SF-36. The scoring for six of the eight subscales is equivalent for the SF-36 and RAND-36, while scoring for the pain and general health scales differs marginally. RAND-36 is a generic measure of HRQoL that has been validated in the general population and for different patient groups.

To our knowledge, no report published in English has investigated HRQoL in CABG patients who subsequently need a percutaneous coronary intervention (PCI) on a saphenous vein graft (SVG). PCI is an established procedure with excellent results in ischemic heart disease patients, particularly when revascularizing the native coronary arteries. On the other hand, PCI of a degenerated SVG often results in a complex percutaneous intervention and its use is debated. Controversial results with a high rate of major adverse cardiac events (MACE) have been observed in both the short and long term. No results have yet been reported regarding PCI of a saphenous vein harvested with the no-touch (NT) technique or treated in any other way during the primary CABG operation. The no-touch technique differs from the conventional (C) technique in that it causes less endothelium damage during the harvesting procedure, and leads to reduced neo-intimal hyperplasia and subsequent atherosclerosis in the long term.

Our group has previously investigated HRQoL in CABG patients who had received a no-touch vein graft, but that study did not compare the no-touch technique with the conventional technique. The aim of this study was to evaluate HRQoL in individuals who needed a PCI of their SVG after a CABG operation. Our specific aim was to compare HRQoL between patients treated with a no-touch SVG and patients who received a conventional SVG.

METHODS

Data Collection

The study cohort consisted of all individuals who underwent a CABG operation at our department between January 1992 and May 2020. The present study included all individuals treated with a PCI on the SVG (stenosed or occluded) between 1 January 2006 and 31 May 2020. The SVG was harvested either with the no-touch technique or with the conventional technique. Two surgeons reviewed all surgical reports to check the categorization of cases into the two groups. The PCI was performed in one of two cardiology departments. The sole exclusion criterion was the execution of PCI less than 30 days after CABG, because this was interpreted as a direct complication of the primary operation due to technical difficulties and not related to the type of vein graft or harvesting technique.

The RAND-36 health survey and information about the study were sent by regular mail to each individual’s address (Supplementary n. 1). In case of non-response, the questionnaire was re-sent at 1-month intervals. All individuals who did not respond the first time were contacted by telephone. Demographic and clinical data were collected from a national quality registry, the Swedish cardiological and cardio-surgical intervention registry (Swedeheart), and from the local hospital register. The study has been approved by the Regional Ethics Review Board in Uppsala (DNR: 2015/242).

This study was registered with ClinicalTrials.gov (no. NCT03999398, 25 June 2019) and the Research and Development registry in Sweden (project no: OLL-242381, 17 October 2017). This was a single-centre study conducted at the centre that invented the no-touch technique and has been using it since 1990. The STROBE checklist for observational studies was followed.

Patient Cohort

Between 1 January 2006 and 30 June 2020, 346 patients (67 NT, 279 C) who had previously undergone a CABG surgery were treated with a PCI on the SVG. Of these, 16 patients were excluded because PCI was performed within 30 days of the CABG procedure. A total of 243 patients were alive at the HRQoL follow-up (55 NT and 188 C) and were asked to participate in the study (Figure 1).

RAND-36 Health Survey

The RAND-36 consists of 36 items grouped into eight multi-item scales: physical functioning (PF), role-functioning/physical (RP), pain (P), general health (GH), energy/fatigue (EF), social functioning (SF), role-functioning/emotional (RE), and emotional well-being (EW). Scale scores are summed and transformed into scales ranging from 0 (worst possible health state) to 100 (best possible state).

Statistical Analysis

Descriptive statistics were calculated as means, standard deviations (SD), and 95% confidence intervals (CI). Categorical variables were summarized with relative frequency distribution. All continuous data were normally distributed and so summarized with mean and standard deviation (SD). A chi-squared test (or Fisher’s exact test if any expected count was <5) was used to compare categorical values between the two groups. An unpaired t-test was performed to compare continuous variables.

Differences in RAND-36 domains between the two treatment groups were tested with the non-parametric Mann-Whitney U test. The magnitudes of group differences were estimated by calculating the effect size (ES; Cohen’s d). ES makes it possible...
Flow diagram inclusion

Patients underwent CABG between January 1992 and May 2020, alive 2006-01-01, with PCI performed in a vein graft

346 PCI performed in a vein graft
(67 NT, 279 C) → 103 dead (12 NT, 91 C)

243 alive (55 NT, 188 C)
 Asked for consent (RAND-36)

78 no answer (7 NT, 71 C)

165 answered the questionnaire
(48 NT, 117 C)

RESULTS

The study included 243 individuals treated with PCI in a stenosed or occluded SVG and alive at the time of the survey. A total of 165 (67.9%) individuals responded to the RAND-36 health survey, 48 (87.3%) in the no-touch group and 117 (62.2%) in the conventional group (Figure 1).

Demographic and Clinical Characteristics

The demographic and surgical characteristics of the two treatment groups are presented in Tables 1 and 2. The demographic characteristics of the two groups were quite similar, with comparable mean age at time of CABG (57.1±8.6 years vs. 57.2±8.1 years, \(P=0.93\)), at time of PCI (\(P=0.72\)), and at time of HRQoL follow-up (73.4±8.8 years vs. 75.4±7.2 years, \(P=0.12\)). Most of the patients were male (around 80%). Risk factors were equally distributed in the two groups, and all comparisons of...
risk factors between the groups were not significant. Regarding the characteristics of the CABG and PCI procedures (Table 2), the two groups showed comparable data in terms of number of anastomoses performed in the CABG, number of successful PCI procedures, frequency of distal embolic protection device usage, and number of thrombectomies performed. The only significant difference was the use of dual antiplatelet therapy at baseline (NT: 54.2% vs. C: 72.6%, P=0.02). However, after PCI, according to local protocol, the patients received dual antiplatelet therapy for at least 1 year if no contraindication was present.

Analysis of the number of cardiovascular events at 1 year (Table 3) and at long-term follow-up (Table 4) confirmed the comparability of the two groups. At 1 year after PCI, no differences in terms of MACE, in-stent restenosis, or re-hospitalization were reported (Table 3). At the time of HRQoL follow-up (Table 4), more events were reported in the conventional group, but the between-group differences were not statistically significant except for the frequency of in-stent restenosis (NT: 6.25% vs. C: 22.2%, P=0.01).

RAND-36 Health Survey

RAND-36 health profiles divided by type of vein graft are presented in Table 5. The patients treated with a no-touch vein graft reported higher mean values in seven of the eight health domains, indicating better HRQoL. Differences between the two groups were statistically significant (P<0.05) in four of the eight domains, all in favour of patients with the no-touch vein graft treatment (P=0.028 for physical functioning, P=0.022 for general health, P=0.010 for energy/fatigue, and P=0.026 for emotional well-being). In terms of ES, the between-group differences were trivial (ES <0.20) for the role-functioning/physical, social functioning, and role-functioning/emotional domains, and small (0.20 ≤ ES <0.50) for the other five domains (Table 5). The largest ESs (>0.40) were noted for the general health and energy/fatigue domains.

PSM analysis (Table 6) confirmed a statistically significant difference between the two groups for the physical functioning (P=0.041) and general health (P=0.002) domains. The difference for the energy/fatigue domain showed a borderline trend towards statistical significance (P=0.056).

DISCUSSION

PCI on SVGs has been in continuous evolution over recent decades. It currently represents approximately 6% of all percutaneous coronary procedures in the US\(^1\). Patients undergoing PCI in SVGs have more early and late adverse cardiac events\(^2\)\(^-\)\(^5\), which may predispose them to a deterioration of their HRQoL and increase the burden for healthcare. This is the first study to show a better HRQoL after PCI in no-touch versus conventional vein grafts.

Few studies have evaluated HRQoL outcomes after PCI in a vein graft. Our group\(^6\)\(^-\)\(^9\) used the EQ-5D-3L questionnaire to examine HRQoL in individuals after CABG, and concluded that graft patency was associated with better HRQoL. However, the HRQoL outcome of the no-touch or conventional vein graft technique was not evaluated separately.

The present study evaluated HRQoL using the RAND-36 health survey in patients treated with no-touch or conventional vein grafts. Our primary analysis showed significant differences between the two treatment groups in four of the eight RAND-36 domains (PF, GH, EF, EW), indicating better HRQoL in the no-touch group at a mean of 5.4±3.6 years after PCI. The effect size estimates (Cohen’s d) indicated better HRQoL in the no-touch group in five domains (PF, GH, EF, EW). EFs were small, but the difference in scale scores on the physical functioning and energy/fatigue scales was approximately 10 points, which has been referred to as a mean group difference. The energy/fatigue domain showed the greatest difference (P=0.010, ES=0.43). A possible explanation for these results could be the higher in-stent restenosis rate after PCI in the

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Table 1. Demographic characteristics.

|                      | No-touch | Conventional | P-value |
|----------------------|----------|--------------|---------|
| Number of patients   | 48       | 117          |         |
| Age at CABG          | 57.1±8.6 | 57.2±8.1     | 0.935   |
| Age at PCI           | 70.1±9.1 | 71.2±8.1     | 0.725   |
| Age at survey response | 73.4±8.8 | 75.4±7.21    | 0.124   |
| Time between CABG and PCI | 13.6±5.9 | 14.1±4.8     | 0.534   |
| Time between PCI and survey | 4.4±3.9 | 5.9±3.5      | 0.021   |
| Male gender          | 38 (79.2%) | 104 (88.9%)  | 0.102   |
| Smoking history (past and present) | 25 (52.1%) | 74 (63.2%)   | 0.276   |
| Hypertension         | 43 (89.6%) | 98 (83.7%)   | 0.622   |
| Diabetes mellitus    | 16 (33.3%) | 37 (31.6%)   | 0.831   |
| Creatinine level     | 83.8±25.0 | 90.4±28.3    | 0.185   |

Values are presented as mean±standard deviation or n (%). Ages and times are given in years, and creatinine is given in micromole/L. Smoking was divided into three categories in the analysis: never smokers, former smokers (more than 1 month ago), current smokers.
Table 2. Surgical and PCI characteristics.

|                                | No-touch | Conventional | P-value |
|--------------------------------|----------|--------------|---------|
| Number of patients             | 48       | 117          |         |
| Number of distal anastomoses   | 3.7±1.1  | 3.6±0.9      | 0.585   |
| Indication for PCI             |          |              |         |
| Effort angina                  | 18       | 40           | 0.686   |
| Acute coronary syndrome        | 30       | 77           |         |
| Number of stenosed vein grafts | 59       | 170          | 0.150   |
| PCI success (restenosis <20%)  | 42 (87.5%)| 104 (88.9%)  | 0.800   |
| Not possible to perform PCI    | 3 (6.3%) | 10 (8.5%)    | 0.758   |
| Distal embolic protection device| 1 (2.1%) | 5 (4.3%)     | 0.673   |
| Thrombectomy performed        | 6 (12.5%)| 9 (7.7%)     | 0.374   |
| Dual antiplatelet therapy      | 26 (54.2%)| 85 (72.6%)   | 0.022   |

Values are presented as mean±standard deviation or n (%). PCI=percutaneous coronary intervention

Table 3. Cardiac events at 1 year.

|                                | No-touch | Conventional | P-value |
|--------------------------------|----------|--------------|---------|
| Number of patients             | 48       | 117          |         |
| Re-angiography during first year|          |              |         |
| None                           | 43 (89.6%)| 102 (87.2%)  | 0.706   |
| 1                              | 5 (10.4%) | 13 (11.1%)   |         |
| 2                              | 0 (0%)    | 2 (1.7%)     |         |
| Cardiac hospitalization during the 1st year | 7 (14.6%)| 23 (19.7%)   | 0.083   |
| In-stent restenosis during the 1st year | 0 (0%)   | 1 (0.8%)     | 1.000   |
| MACE during the 1st year        | 7 (14.6%)| 23 (19.7%)   | 0.708   |

Values are presented as n (%). MACE=major adverse cardiac event

Table 4. Cardiac events at health-related quality of life follow-up.

|                                | No-touch | Conventional | P-value |
|--------------------------------|----------|--------------|---------|
| Number of patients             | 48       | 117          |         |
| Re-angiography at follow-up    |          |              |         |
| None                           | 35 (72.9%)| 72 (61.5%)   | 0.091   |
| 1                              | 11 (22.9%)| 26 (22.2%)   |         |
| 2                              | 1 (2.1%)  | 9 (7.7%)     |         |
| 3                              | 1 (2.1%)  | 10 (8.5%)    |         |
| In-stent restenosis at follow-up| 3 (6.3%)  | 26 (22.2%)   | 0.015   |
| Major adverse cardiac event at follow-up | 13 (27.1%)| 46 (39.3%)   | 0.072   |

MACE=major adverse cardiac event
Table 5. Results of the RAND-36 health survey divided by type of vein graft.

| RAND-36 domains | No-touch (n=48) | Conventional (n=117) | Difference between groups | P-value | Effect size |
|-----------------|----------------|----------------------|--------------------------|---------|-------------|
|                 | Mean | SD  | 95% CI | Mean | SD  | 95% CI | Mean | 95% CI |         |
| PF              | 68.6 | 26.7 | 62.5-77.9 | 58.4 | 27.6 | 53.8-63.9 | 10.3 | 1.0-19.5 | 0.028 | 0.38 |
| RP              | 47.4 | 42.6 | 36.2-62.6 | 40.3 | 40.0 | 32.6-47.6 | 7.0 | -6.8-20.1 | 0.352 | 0.17 |
| P               | 71.8 | 25.5 | 64.2-79.4 | 65.0 | 29.3 | 59.9-70.7 | 6.8 | -2.9-16.5 | 0.171 | 0.24 |
| GH              | 61.0 | 19.3 | 55.2-66.7 | 52.6 | 21.0 | 49.0-56.8 | 8.3 | 1.3-15.4 | 0.022 | 0.41 |
| EF              | 65.4 | 21.8 | 58.9-71.9 | 55.8 | 22.7 | 51.2-59.9 | 9.6 | 1.9-17.4 | 0.010 | 0.43 |
| SF              | 77.2 | 27.5 | 69.1-85.4 | 72.9 | 27.6 | 68.2-78.4 | 4.3 | -5.2-13.8 | 0.243 | 0.15 |
| RE              | 70.1 | 40.2 | 60.8-84.1 | 69.7 | 39.5 | 62.9-77.7 | 0.4 | -13.1-13.9 | 0.851 | 0.10 |
| EW              | 81.0 | 21.0 | 74.8-87.3 | 74.9 | 20.4 | 71.3-79.1 | 6.1 | -0.9-13.2 | 0.026 | 0.29 |

Effect size was calculated according to Cohen’s $d$ and categorized as trivial (0.0 to <0.2), small (0.2 to <0.5), medium (0.5 to <0.8), or large ($\geq$0.8). Significant P-values are shown in bold. Effect sizes categorized as at least “small” are underlined.

Table 6. Treatment effects on the RAND-36 domains of no-touch versus conventional vein graft (propensity score matching).

| RAND-36 domains | Average treatment effect (95% CI) | P-value |
|-----------------|----------------------------------|---------|
| PF              | 9.31 (0.38-18.24)                | 0.041   |
| RP              | 6.03 (-8.27-20.33)               | 0.409   |
| P               | 6.83 (-2.92-16.57)               | 0.170   |
| GH              | 10.31 (3.85-16.76)               | 0.002   |
| EF              | 8.72 (-0.24-17.68)               | 0.056   |
| SF              | 3.86 (-5.73-13.45)               | 0.430   |
| RE              | -0.82 (-15.13-13.49)             | 0.911   |
| EW              | 4.62 (-5.78-15.02)               | 0.384   |

EF=energy/fatigue; EW=emotional well-being; GH=general health; P=pain; PF=physical functioning; RE=role-functioning/emotional; RP=role-functioning/physical; SF=social functioning

conventional group, and its consequences in terms of quality of life. Further clarifications in terms of clinical outcomes are under investigation with a larger patient cohort (ClinicalTrials.gov no. NCT03999398).

Few studies have estimated the minimal clinically important difference (MCID) for the RAND-36/SF-36 scales in cardiopathic populations. Bjorner et al. evaluated MCID for energy/fatigue in individuals with chronic conditions including congestive heart failure, and recommended a MCID of 5-10 points[23]. In the present study, the difference between the no-touch and the conventional groups was 9.6 points for energy/fatigue, indicating a clinically important difference.

The patients who received a no-touch vein graft estimated their physical health (PF, RP, P, GH) more positively than the conventional group, although the differences in RP and P were not significant. The positive effect on physical health in the no-touch group was confirmed by the PSM analysis, showing statistically significant differences in two domains (PF, GH). Comparison of the average treatment effects according to the PSM analysis (Table 6) and differences between treatment groups according to the primary analysis (Table 5) showed that the results were roughly equal. The general similarity between the primary analysis and the PSM indicates that no predictor variable behaved as a confounder in the analysis.

The confirmed positive effect on the physical health components supports the clinical relevance of the HRQoL difference between the two techniques, since the scales that primarily measure physical health are particularly associated with the health condition in cardiac and cardio-operated patients[24].

Hokkanen et al.[6] used RAND-36 to examine both short-term (1 year) and long-term (12 years) changes in HRQoL in patients treated with CABG. Their 1-year results[23] demonstrated that all RAND-36 domains improved significantly; however, this
improvement was significant only among patients under 75 years. At the 12-year follow-up, significant improvements were observed in all RAND-36 domains except general health. Moreover, patients younger than 65 years at baseline maintained their physical health status after 12 years, whereas older patients reported a pronounced decrease in both physical and mental component summary scores. The present study was similar in terms of follow-up time, although it was not prospective and did not analyse changes over time. However, an analysis of our results for patients under 65 years showed RAND-36 scores comparable to those reported by Hokkanen et al., particularly in the no-touch group. It is noteworthy that the general health domain did not improve in the earlier study, with a mean value of 54.2 at baseline and 54.5 at 12 years. Our study found a significant difference in general health between the no-touch and conventional groups, with a mean value of 61.0 in the no-touch group; the effect size was in the upper range of a small difference (ES=0.41). This result can be explained by the already-known fact that no-touch vein graft patients tend to have reduced atherosclerosis over time and lower rates of adverse cardiac events, with an expected positive impact on general health.

Few studies have evaluated HRQoL after PCI using SF-36 or RAND-36. In 2008, Gümüş et al. reported SF-36 results for octogenarians treated with PCI that partially differ from our results. Their study group showed a markedly lower mean value on the physical functioning scale (41±28) than we found in our study, which may be explained by the demographic characteristics of the study population (patients over 80 years). However, scores on the pain, role-emotional, and mental well-being scales were comparable with the results for the conventional group in the present study. Cohen et al. investigated HRQoL using the SF-36 after either PCI or CABG at 1 month, 6 months, and 1 year after the intervention, finding no change in HRQoL at the 1-year follow-up. Their SF-36 results after 1 year were equivalent to those observed in the no-touch group in our study, except for physical functioning, which was better in the study by Cohen et al., and mental health/emotional well-being, which was better in our study. This comparison between the PCI of a native vessel and the PCI of a no-touch vein graft suggests the hypothesis that no-touch SVGs are as suitable for PCI as a native coronary artery. A better HRQoL score thus correlates with the reduced intimal damage and subsequent atherosclerosis in the long term during the no-touch vein harvesting.

Limitations of the Study

The main limitation of the present study is the small number of individuals in the no-touch group (n=48), despite the high response rate (87.3%). However, the power was sufficient to detect significant differences between the two study groups on four of the eight RAND-36 scales. We also calculated effect sizes, which are independent of sample size, to estimate the magnitude of group differences. A second limitation is the retrospective study design, which means that HRQoL data before the operation were not available. Another possible limitation is the difference between the study groups in terms of follow-up time. Individuals treated with the no-touch technique had a shorter follow-up time than the conventionally treated patients (4.4 vs. 5.9 years, Table 1). According to Hokkanen et al., a main predictor of HRQoL after CABG is the initial age at CABG, with declining RAND-36 scores at the 12-year follow-up in patients older than 65 years at the time of the CABG. Our study groups showed comparable age at time of CABG, PCI, and HRQoL follow-up, indicating that age was not a confounding factor in the comparison between the two groups.

CONCLUSION

At a mean follow-up of 5.4 years, patients who received PCI in no-touch SVGs showed significantly better HRQoL than those who received PCI in conventional vein grafts.

ACKNOWLEDGEMENTS

Lenore Haugland, medical secretary, and Mia Karlsson, MD.

Financial support: this work was supported by Region Örebro County through the regional research board (grant OLL-935188, 18 January 2020).

No conflict of interest.

| Authors' Roles & Responsibilities |                      |                      |                      |                      |
|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| GF                               | Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; drafting the work or revising it critically for important intellectual content; final approval of the version to be published |
| JK                               | Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; drafting the work or revising it critically for important intellectual content; final approval of the version to be published |
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| NS                               | Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; final approval of the version to be published |
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Braz J Cardiovasc Surg 2022;37(4):430-438
**Supplementary 1 - Patient Consensus (in original language).**

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**Resultat av PCI-behandling i vengraft**

**Bakgrund och syfte**
Du har tidigare genomgått ballongvidgning i kranshärt (PCI). Härmed tillfrågas du om att delta i ett forskningsprojekt. Läs noga igenom nedanstående information innan du bestämmer dig. Tveka inte att fråga om något är oklart.

Denna studie handlar om resultatet efter ballongvidgning i kranshärt efter kranshärtoperation. Vi vill värdera om typen av bypass-kärl påverkar resultatet av ballongvidgning. Detta kan hjälpa oss att i framtiden bättre välja vilken operationsmetod som ska användas.

**Förfrågan om deltagande**
Vi vill fråga om tillstånd att läsa data om dina operationer i samt läsa dina journaler vid Kärl-Thoraxkliniken i Örebro samt Kardiologkliniken i Örebro alternativt Hjärt- och akutmdecikliniken i Karlstad. Vi vill också fråga om tillstånd att granska bilderna och läsa utlåtandet från den ballongvidgning som utförts. Dessutom ber vi att du besvarar bifogad enkät om ditt aktuella hälsoläge.

**Hur går studien till?**
Om du vill delta ber vi att du skriver under bifogat formulär, fyller i enkäten och skickar in det i bifogat kuvert. Inga övriga åtgärder planeras.

**Hantering av data och sekretess**
Under studien kommer dina personuppgifter att hanteras kodade. Kodnyckeln med vilken det går att koppla uppgifterna till dig kommer endast att vara tillgänglig för mig och mina medarbetare. Ingen obehörig kan få dem.

I enlighet med PUL (personuppgiftslagen) har du rätt att en gång per år kostnadsfritt få utdrag ur registret och veta vilka uppgifter som finns registrerade om dig. Du skall i så fall konstata oss.

Studien är godkänd av regionala etikprövningsnämnden i Uppsala.

**Frivillighet**
Deltagandet är helt frivilligt och du kan avbryta deltagandet när som helst utan att behöva säga varför och utan att det påverkar det fortsatta omhändertagandet. De data som samlats in fram till avbrytandet kommer att analyseras.

**Ansvariga**

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**Brazilian Journal of Cardiovascular Surgery**

**Braz J Cardiovasc Surg 2022;37(4):430-438**

Ferrari G, et al. - Quality of Life After PCI in No-Touch and Conventional Vein Grafts