



Informed Consent before coronary angiography and percutaneous coronary intervention from the patient's perspective: A picture is worth a thousand words

A. Brand^{a,h,*}, C. Crayen^b, A. Hamann^c, S. Martineck^d, L. Gao^e, H. Brand^f, S.M. Squier^g, K. Stangl^{a,h}, F. Kendel^f, V. Stangl^{a,h}

^a Charité – Universitätsmedizin Berlin, Department of Cardiology and Angiology, Campus Charité Mitte, Charitéplatz 1, 10117 Berlin, Germany

^b Freie Universität Berlin, Department of Education and Psychology, Habelschwerdter Allee 45, 14195 Berlin, Germany

^c mintwissen – science communication agency and publishing house, Paulusstr. 11, 40237 Düsseldorf, Germany

^d Sophia Martineck, Kollwitzstraße 52, 10405 Berlin, Germany

^e Charité – Universitätsmedizin Berlin, Department of Nephrology and Medical Intensive Care, Campus Virchow Klinikum, Augustenburger Platz 1, 13353 Berlin, Germany

^f Charité – Universitätsmedizin Berlin, Institute of Gender in Medicine, Augustenburger Platz 1, 13353 Berlin, Germany

^g The Pennsylvania State University, Brill Professor Emeritus of English and Women's, Gender and Sexuality Studies, University Park, and Freie Universität Berlin, Einstein Visiting Fellow, PA 16802, United States

^h DZHK (German Centre for Cardiovascular Research), Partner Site Berlin, Germany

ARTICLE INFO

Keywords:

Informed Consent
Patient Reported Outcome Measures
Coronary angiography
PCI
Medical graphic narratives

ABSTRACT

Background: Patients scheduled for coronary angiography may feel insufficiently informed about the planned procedure. We aimed to evaluate the patient-rated quality of the Informed Consent (IC) process and to investigate the efficacy of medical graphics to assist and improve the IC procedure.

Methods: A graphic-based information brochure illustrating central steps of the procedure was created in collaboration with scientific illustrators. In a randomized, controlled, prospective trial, 121 patients undergoing coronary angiography/PCI were randomized to a group obtaining the usual IC (Control group) or to a group that additionally obtained a graphic-based IC (Comic group). The perceived quality of the IC was compared between groups using single items of the Client Satisfaction Questionnaire-8 and self-designed single items.

Results: Only 67.8% of patients stated to have completely read the standard written IC sheet. The quality of the IC was perceived to be very good in 45.0% of patients in the Comic group compared to 24.6% in the Control group ($p = .023$). 57.4% of the Control group compared to 76.7% of the Comic group stated that all of their questions were satisfactorily addressed ($p = .015$). 43.3% of the Comic group, in contrast to only 18.0% of the Control group, declared to feel „very satisfied“ with the obtained IC procedure ($p = .002$). The acceptance of this new IC approach was very high: no patient expressed feelings of not being taken seriously when reading medical graphics.

Conclusions: Our data confirm pronounced limitations of the usual IC practice. The use of medical graphics positively impacts on patient-evaluated endpoints and may significantly improve the IC procedure.

1. Introduction

Patient Reported Outcome Measures (PROMs) are of increasing importance in cardiovascular medicine. Current guidelines on

myocardial revascularization acknowledge the growing interest of PROMs as a central feature of high-quality patient care and emphasize its importance in the shared decision making process [1]. However, data on PROMs investigating the Patient Informed Consent (IC) as an integral

* Corresponding author at: Charité – Universitätsmedizin Berlin, Department of Cardiology and Angiology, Campus Charité Mitte, Charitéplatz 1, 10117 Berlin, Germany.

E-mail addresses: anna.brand@charite.de (A. Brand), claudia.crayen@fu-berlin.de (C. Crayen), ah@mintwissen.com (A. Hamann), info@martineck.com (S. Martineck), linde.gao@charite.de (L. Gao), hannah.brand1@charite.de (H. Brand), sxs62@psu.edu (S.M. Squier), karl.stangl@charite.de (K. Stangl), friederike.kendel@charite.de (F. Kendel), verena.stangl@charite.de (V. Stangl).

<https://doi.org/10.1016/j.ijcha.2022.101076>

Received 1 June 2022; Accepted 22 June 2022

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part of the procedure from a patient's perspective are sparse, even though available data suggest that patients scheduled for coronary revascularization are insufficiently informed about the procedure [2] as a prerequisite for active patient participation. We previously reported beneficial effects of *medical graphic narratives* (see Fig. 1) to inform patients about the planned coronary angiography and percutaneous coronary intervention (PCI), showing improvement of patient comprehension and periprocedural anxiety compared to standard care [3]. This analysis aims to assess investigate patient-evaluated variables, such as the perceived quality of the Patient IC, the feeling of having been adequately informed about the planned procedure, feelings of anxiety before the intervention, and the patient's acceptance of the IC material before the planned procedure; and to analyze potential beneficial effects of an additional graphic-based information brochure containing *medical graphic narratives* on these endpoints.

2. Methods

The study protocol and primary endpoints of the main trial have been published [3]. In brief, a patient brochure using *medical graphic narratives* to illustrate central steps of the procedure, risks, treatment alternatives, and behavioral measures was created in collaboration with scientific illustrators [4]. For this randomized monocentric pilot trial, we recruited consecutive patients undergoing first-time elective coronary angiography with potential PCI between October 2016 and January 2018 at the Clinic of Cardiology, Charité - University Medicine Berlin, Campus Mitte [3]. Patients were eligible for inclusion if they were aged > 18 years, were able to understand, speak, read and write German, and consented to participate in our study. Patients who had previous cardiac catheterization, poor German language skills or had severe cognitive or psychiatric conditions were excluded.

Patients were randomized in a 1:1 fashion to a group obtaining the standard Patient IC (conversation with a physician and written IC sheet; Control group, n = 61) and into a group that additionally obtained an information brochure illustrating central IC-related aspects using *medical graphic narratives* (Comic group; n = 60) [3]. PROMs evaluating self-rated patient satisfaction, acceptance of this new graphical IC approach, and the perceived quality of the delivered IC were investigated using single items of the validated Client Satisfaction Questionnaire-8 (CSQ-8) and self-designed single items. All items were assessed using a 4-point rating scale. Significance of differences were tested using the Fisher's exact test. A p-value < 0.05 was considered significant.

The study protocol conforms to the ethical guidelines of the Declaration of Helsinki and was approved by the institutional ethics committee of the Charité - Universitätsmedizin Berlin (registration number EA1/196/16). All patients provided verbal and written informed consent to participate in the study. The trial is registered with the German Registry of Clinical Studies (DRKS00012493). The study was funded by the Friede Springer Stiftung Berlin, Germany. The study sponsor did not participate in the study procedure and was neither involved in the planning of study design; nor in the collection, analysis, and interpretation of data; in writing of the report; nor in the decision to submit the paper for publication.

3. Results

Demographic and clinical characteristics of the study cohort have been previously described [3]. In brief, 59 (48.8%) of the study participants were women, and 66 (54.5%) had a university or polytechnic degree [3]. The current analysis of PROMs demonstrated a limited overall patient satisfaction with and perceived quality of the patient IC in the Control group while suggesting beneficial effects of additionally using *medical graphic narratives* to assist the IC procedure on these outcomes (Table 1). Moreover, only 82 (67.8%) of patients in both groups stated to have completely read the standard written patient IC sheet. The

graphical information brochure, in contrast, was completely read by 52 (86.7%) of patients assigned to the Comic group. Only 56 of all 121 patients (47.9%) declared to have completely understood all the explanations contained in the standard written IC sheet while 80.0% of the patients in the Comic group stated to have completely understood all the explanations of the graphic-based information brochure. The overall acceptance of the patient comic was very high: all patients in the Comic group denied feelings of not being taken seriously by being informed about the planned procedure using a graphical format.

4. Discussion

Even though it is well accepted that delivering an adequate and understandable patient IC constitutes an integral part of the procedure for legal - but above all - for ethical reasons [5], our data confirm profound limitations of the current IC practice before coronary angiography and PCI: A substantial proportion of patients in the Control group felt insufficiently informed about the planned procedure and claimed a low quality of and satisfaction with the obtained Patient IC. The importance of these patient-centered variables as indicators for high-quality cardiovascular medicine is increasingly recognized bringing PROMs, next to "hard" medical outcome data, into focus in future cardiovascular research [6]. In contrast to the current IC practice which confronts patients with long and complex text, graphic narratives, using illustrations in juxtaposition with simple text [7], may increase patient satisfaction and comfort by conveying complex information in a concise manner independent of cultural and educational background. The use of additional graphic-based information is a new, feasible approach that has been shown to significantly increase patient comprehension in a pilot trial [3]. The present data additionally suggest beneficial effects on patient-centered variables such as patient satisfaction and comfort as well as on the perceived quality of the patient IC, and furthermore indicate a high acceptance of this new graphic-based IC method.

Our study holds some limitations. As a pilot trial with no available data to be used for study planning, the aim of the study was to explore potential effects of using *medical graphic narratives* to improve the IC procedure. For that reason, our study holds a relatively low number of cases, and was performed at a single center. Furthermore, concerns could be raised regarding the acceptance of comic style drawings in general and especially in patients facing stressful situations, since graphic narratives may be perceived as superficial or simplistic. However, the patient acceptance of the delivered *medical graphic narratives* was very high with no patient stating feelings of not being taken seriously.

To sum up, the present data on PROMs confirm major unmet needs of our current Patient IC practice. The additional use of *medical graphic narratives* to assist the IC procedure significantly improves periprocedural patient-reported variables.

5. Note

Clinical trial registration number: German Registry of Clinical Studies (DRKS00012493).

Acknowledgement of grant support: The study was funded by the Friede Springer Stiftung, Berlin, Germany.

CRediT authorship contribution statement

A. Brand: Conceptualization, Funding acquisition, Methodology, Formal analysis, Project administration, Supervision, Validation, Writing – original draft. **C. Crayen:** Methodology, Formal analysis, Software, Validation, Writing – review & editing. **A. Hamann:** Conceptualization, Methodology, Software, Visualization, Writing – review & editing. **S. Martinek:** Conceptualization, Methodology, Software, Visualization, Writing – review & editing. **L. Gao:** Methodology, Data curation, Investigation, Software, Writing – review & editing.

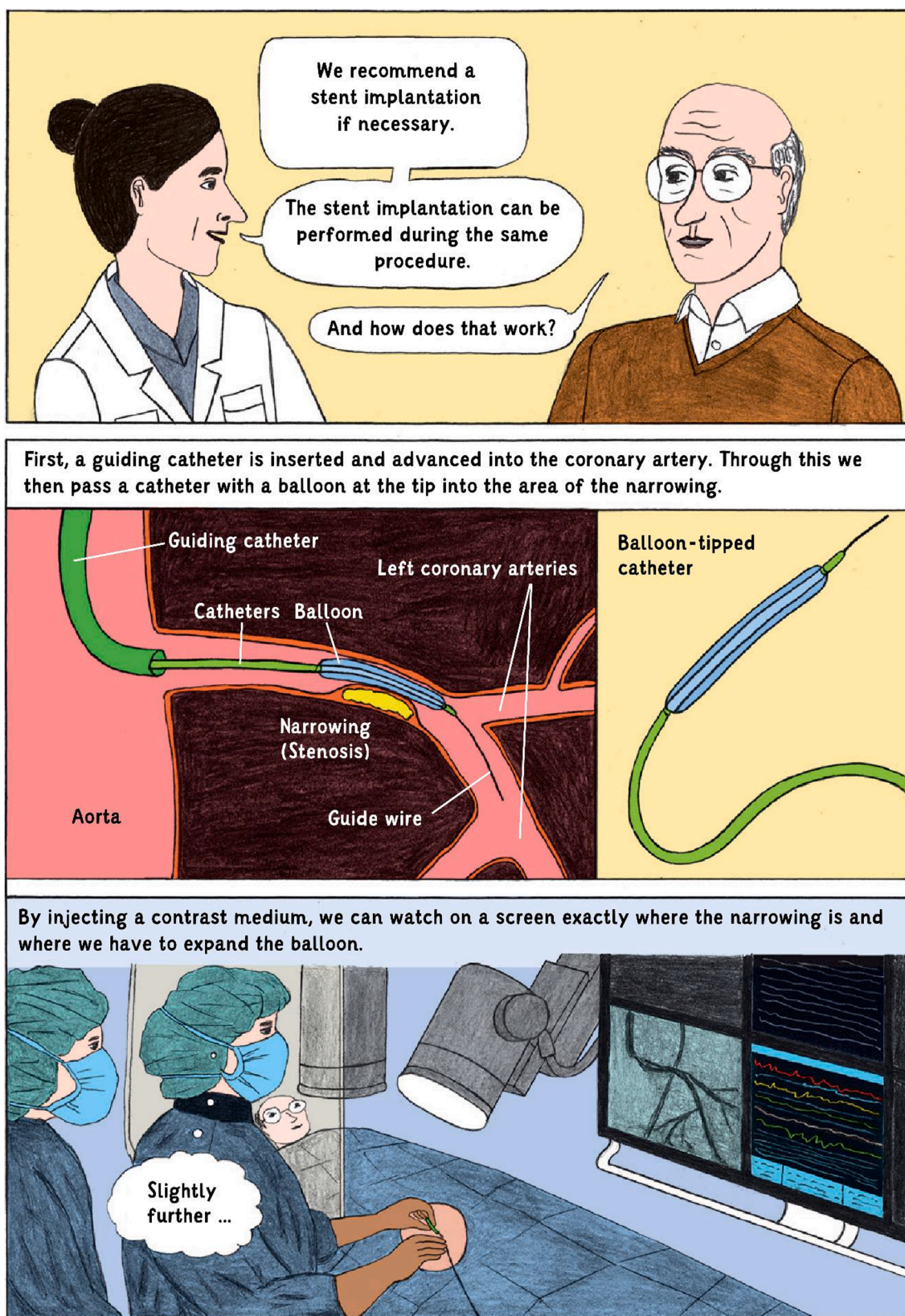


Fig. 1. Excerpt of the information brochure: *Medical graphic narratives* to illustrate central IC-related aspects in a concise and understandable manner. Reproduced with permission from Brand et al. *Annals Graphic Medicine - Patient-Informed Consent*. *Annals of Internal Medicine*. 2019 Apr 16;170(8):W90-W106. URL ©American College of Physicians.

Table 1

PROMs evaluating the Patient IC before coronary angiography and PCI, Control vs. Comic group.

| | Control group (n = 61) n (%) | Comic group (n = 60) n (%) | <i>p value</i> |
|---|------------------------------------|----------------------------------|----------------|
| <i>Rated quality of patient IC</i> | | | |
| Very good | 15 (24.6) | 27 (45.0) | <i>0.023</i> |
| Good | 40 (65.6) | 32 (53.3) | |
| Rather low | 6 (9.8) | 1 (1.7) | |
| <i>Patient IC fulfilled expectations</i> | | | |
| Yes, definitely | 14 (23.0) | 24 (40.0) | <i>0.012</i> |
| Rather yes | 42 (68.9) | 36 (60.0) | |
| Rather not | 5 (8.2) | 0 | |
| <i>Patient IC adequately informed about the procedure</i> | | | |
| Yes | 29 (47.5) | 41 (68.3) | <i>0.016</i> |
| Rather yes | 28 (45.9) | 19 (31.7) | |
| Rather not | 4 (6.6) | 0 | |
| <i>Recommend obtained patient IC to a friend</i> | | | |
| Yes, definitely | 21 (34.4) | 31 (51.7) | <i>0.011</i> |
| Rather yes | 34 (55.7) | 29 (48.3) | |
| Rather not | 6 (9.8) | 0 | |
| <i>IC helped to feel calmer before the procedure</i> | | | |
| Yes, definitely | 13 (21.3) | 23 (38.3) | <i>0.014</i> |
| Rather yes | 34 (55.7) | 33 (55.0) | |
| Rather not | 14 (23.0) | 4 (6.7) | |
| <i>Satisfied with the obtained patient IC</i> | | | |
| Yes, definitely | 11 (18.0) | 26 (43.3) | <i>0.002</i> |
| Rather yes | 47 (77.0) | 34 (56.7) | |
| Rather not | 3 (4.9) | 0 | |
| <i>All questions were satisfactorily answered</i> | | | |
| Yes, definitely | 35 (57.4) | 46 (76.7) | <i>0.015</i> |
| Rather yes | 21 (34.4) | 14 (23.3) | |
| Rather not | 5 (8.2) | 0 | |

Methodology. **H. Brand:** Conceptualization, Methodology, Writing –

review & editing. **S.M. Squier:** Conceptualization, Methodology, Writing – review & editing. **K. Stangl:** Conceptualization, Methodology, Supervision, Writing – review & editing. **F. Kendel:** Conceptualization, Methodology, Writing – review & editing. **V. Stangl:** Conceptualization, Methodology, Formal analysis, Project administration, Supervision, Writing – original draft.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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