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Is the folk medicine known as "The Secret" efficient in reducing bleeding after percutaneous coronary procedures?: a double-blinded, randomised trial

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ABSTRACT

Aim Percutaneous coronary interventions require an arterial approach and administration of antithrombotic drugs. This may lead to bleeding complications. The aim of this study was to test whether "The Secret" – a pagan prayer – is effective in reducing post-interventional bleeding.

Design Randomised controlled trial.

Setting Monocentric, tertiary care centre.

Participants From January to July 2022, 200 patients (aged >18 years) undergoing elective coronary angiography were included in the study.

Intervention The intervention group received "The Secret" in addition to the normal procedure. The control group was treated according to standard practice.

Main outcome measures The primary outcome was the rate of in-hospital bleeding according to the Bleeding Academic Research Consortium (BARC) consensus definition.

Results The rate of bleeding was similar in both groups ("The Secret" group vs control group) with 16% versus 14% (p=0.69) of BARC 1, 12% versus 13% (p=0.81) of BARC 2, and 0% versus 0% of BARC 3 and 5 (p=1.00). Most (76%) of the participants believed that "The Secret" would be efficient in preventing bleeding.

Conclusions This study demonstrates no effect on bleeding after percutaneous coronary procedures. A large majority of our study population believe that "The Secret" can have a positive effect on their hospital care.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Percutaneous cardiac procedures are associated with a risk of bleeding. "The Secret" is a pagan prayer that is considered a popular complementary medicine in Europe that may limit bleeding. No study has tested whether this folk medicine works.

WHAT THIS STUDY ADDS

⇒ Most participants believed that "The Secret" would be beneficial but there was no effect on bleeding. "The Secret" is best understood as magical thinking.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ "The Secret" is of no relevance in cardiology other than perhaps limiting the anxiety of superstitious believers, a phenomenon deserving of scientific investigation.

> When the attic is on fire, there is no longer any point to pray or scrub the floor. However, it is more practical to pray.
> Karl Kraus

INTRODUCTION

For centuries, humans have relied on medical beliefs based on myth or superstition. Despite recent technical and scientific advances, some of these beliefs and associated practices persist. "*Le Secret*", a charm for staunching blood that has been used for several centuries in Switzerland, is considered a complementary medicine as defined by Zollman and Vickers.[1] This rite consists of performing a healing formula or prayer which is supposed to mobilise superior forces to help cure the patient. This blood charm is widely practised in the French-speaking part of Switzerland and achieved an inscription on the intangible heritage list of the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 2012.[2] The "formula" can be practised on site or remotely by an initiated "Secret Maker". The name "Secret" comes from its oral and clandestine transmission from one "Maker" to another.[3] "The Secret" is a popular and reputed complementary medicine,[3] and the reason for its good reputation stems from the fact that it is available free of charge and is supposedly without side effects.

Despite the prevalence of the practice and its use in hospital departments,[2] no study has to date tested its clinical efficacy.

In the French-speaking part of Switzerland, it is not uncommon for patients to ask caregivers for "The Secret" to avoid bleeding during and after an intervention. The cardiology department has one of the highest risks of bleeding in the hospital. Bleeding represents a risk of complication for the patient,[4] and is costly for the hospital.[5] In contrast, "The Secret" is simple, free, and readily obtained via a call to the "Maker". In practice, it is a simple call. We therefore wished to test the effectiveness of "The Secret" in everyday clinical practice.

METHODS

Study population and randomisation

We conducted a single-centre, double-blinded, randomised controlled trial with an allocation ration of 1:1.

All patients admitted to University and Hospital Fribourg for an elective invasive coronary procedure (diagnostic coronary angiography and/or percutaneous coronary intervention) aged over 18 years were eligible for inclusion. Patients having already contacted a "Secret Maker" to speak the formula on their behalf prior to the coronary angiography and those unable or unwilling to provide written informed consent and/or to participate in clinical follow-up were excluded. Patients with a major procedural complication (anaphylaxis, stroke, periprocedural myocardial infarction, pulmonary embolism, death) were likewise excluded.

Baseline patient and procedural characteristics were collected by dedicated study nurses during the index hospitalisation for elective coronary angiography. Clinical outcome was collected at discharge.

All patients underwent coronary angiography via the radial and/or femoral artery. Coronary angiography was performed according to good clinical practice using 5F or 6F diagnostic catheters at the operator's discretion. Treatment modalities including devices used during percutaneous coronary intervention and antithrombotic management were at the physician's discretion and according to the local standard of care at the time of the intervention.

A research nurse randomly assigned patients on the day of the intervention using sealed envelopes. Patients were randomised to receive standard care (C-group) or to receive standard care and "The Secret" (S-group).

The patients, cardiologists and nurses assessing bleeding outcomes were unaware of the patient's group or the identity of the "Secret Maker". Bleeding outcomes were classified and adjudicated internally by an event adjudication committee.

For the intervention group we asked "Secret Makers" to give the formula after study inclusion but prior to coronary angiography. The "Secret Makers", 15 men and woman from an official list,[6] agreed to participate in the study and were randomly selected on the same day from that list. The full name and birthday of the respective patient in the intervention group was communicated bytelephone to the Secret Maker, who then performed the blood charm sometime between study inclusion and coronary angiography. The exact wording of the charm to staunch bleeding was unknown to the investigators and might have differed from one "Secret Maker" to another.

All factors that could affect bleedings outcomes before, during and after the procedure were collected the day of the intervention and then compared by group. We also considered patients with high bleeding risk (HBR) depending on the definition of Academic Research Consortium High Bleeding Risk (ARC-HBR). Major and minor criteria are described by Urban *et al*.[7] Patients were at HBR if at least one major or two minor criteria were met.

Clinical endpoints

The primary outcome was the rate of in-hospital bleeding according to the Bleeding Academic Research Consortium (BARC) consensus definition.[8]

The null hypothesis was that there is no difference in bleeding rate between the two groups, and the alternative hypothesis was that there was a significant difference in bleeding rate in one of the two groups. The study complied with the Helsinki Declaration and was approved by the local ethics committee (CER-VD 2021–01877). All patients provided written informed consent.

Statistical analysis

Categorical variables were reported as counts and percentages; continuous variables were reported as means and standard deviations. Normality was assessed by the computation of Q-Q plots and the Shapiro–Wilk test. Continuous variables were analysed using the Student's t-test or the Wilcoxon rank-sum test per distribution. Categorical variables were compared using chi-square or Fisher exact test as appropriate. All statistical analyses were performed using dedicated software (StataCorp LP, College Station, Texas) at a two-tailed significance level of alpha=0.05.

RESULTS

Study population

Between January 2022 and July 2022, 238 patients were screened for enrolment. Thirty-four patients refused to participate and four had already called on a "Secret Maker" prior to the intervention to prevent bleeding. The final study population consisted of 200 patients. One hundred patients were randomised to receive "The Secret" and 100 patients were randomised to the control group.

Baseline patient and procedural characteristics

Baseline patient and procedural characteristics can be found in table 1. Mean age was 68±9 years and 74% (n=147) of the sample were men. Hypertension was

Table 1 Baseline patient and procedural characteristics

Characteristic	All n=200	Secret n=100	Control n=100	P value
Baseline patient characteristics				
Age, years	68±9.9	68±10.4	68±9.4	0.99
Male	147 (73.5)	76 (76.0)	71 (71.0)	0.42
Smoker	41 (20.5)	21 (21.0)	20 (20.0)	0.86
Hypertension	105 (52.5)	46 (46.0)	59 (59.0)	0.07
Diabetes mellitus 2	39 (19.5)	14 (14.0)	25 (25.0)	0.05
Dyslipidaemia	109 (54.5)	47 (47.0)	62 (62.0)	0.03
BMI, kg/m^2	28 (25–30)	27 (25–30)	28 (25–30)	0.98
Believes in "The Secret"	150 (75.0)	73 (73.0)	77 (77.0)	0.51
Preprocedural medication				
Aspirin	102 (51.0)	53 (53.0)	49 (49.0)	0.57
Clopidogrel	6 (3.0)	2 (2.0)	4 (4.0)	0.41
Anticoagulation	17 (8.5)	6 (6)	11 (11)	0.21
AVK	4 (2.0)	0 (0.0)	4 (4.0)	0.12
DOAC	13 (6.5)	6 (6.0)	7 (7.0)	0.77
DAPT	43 (21.5)	20 (20.0)	23 (23.0)	0.49
Aspirin + clopidogrel	8 (4.0)	3 (3)	5 (5)	0.72
Aspirin + prasugrel	35 (17.5)	17 (17.0)	18 (18.0)	0.85
Aspirin + DOAC	3 (1.5)	2 (2.0)	1 (1.0)	1.00
Clopidogrel + DOAC	1 (0.5)	0 (0.0)	1 (1.0)	1.00
None	28 (16.0)	17 (17.0)	11 (11.0)	0.22
HBR-ARC bleeding risk				
HBR-ARC major criterion	45 (22.5)	20 (20.0)	25 (25.0)	0.40
HBR-ARC minor criterion	45 (22.5)	20 (20.0)	25 (25.0)	0.40
Creatinine, µM/L	79 (67–91)	77 (68–90)	81 (66–91)	0.73
CKD-EPI, mL/min	81 (69–92)	81 (69–91)	82 (69–92)	0.95
Haemoglobin, g/dL	14 (13–15)	14 (13–15)	14 (13–15)	0.14
Thrombocytopenia (<100×10^9/L)	3 (1.5)	0 (0.0)	3 (3.0)	0.08
Treatment for a cancer <12 months	7 (3.5)	3 (3.0)	4 (4.0)	0.70
Chronic bleeding	5 (2.5)	3 (3.0)	2 (2.0)	0.65
Procedure				
Vessels diseased				
0-vessel	112 (56.0)	58 (58)	54 (54)	0.57
1-vessel	58 (29.0)	26 (26.0)	32 (32.0)	0.35
2-vessel	24 (12.0)	12 (12.0)	12 (12.0)	1.00
3-vessel	6 (3.0)	2 (2.0)	4 (4.0)	0.68
Lesions, n	0 (0–1)	0 (0–2)	0 (0–1)	0.86
Vascular access				
Radial	115 (57.5)	51 (51.0)	64 (64.0)	0.06
Femoral	76 (38.0)	44 (44.0)	32 (32.0)	0.08
Mixed	9 (4.5)	5 (5.0)	4 (4.0)	1.00
6 F sheath	189 (94.5)	95 (95.0)	94 (94.0)	0.94
Procedure with stent implantation	87 (43.5)	42 (42.0)	45 (45.0)	0.66
Stents by procedure, n	2 (1–2)	2 (1–2)	1 (1–2)	0.05
Duration, min	23 (11–40)	25 (11–41)	21 (11–37)	0.83
Procedural medication				
Aspirin	6 (3.0)	1 (1.0)	5 (5.0)	0.21

Continued

Table 1 Continued

Characteristic	All n=200	Secret n=100	Control n=100	P value
Heparin	125 (62.5)	64 (64.0)	61 (61.0)	0.66
Aspirin + heparin	24 (12.0)	7 (7.0)	17 (17.0)	0.03
Aspirin + heparin + tirofiban	1 (0.5)	1 (1.0)	0 (0.0)	1.00
None	44 (22.0)	27 (27.0)	17 (17.0)	0.09
Given postprocedural medication				
P2Y12 inhibitor	78 (39.0)	37 (37.0)	41 (41.0)	0.97
Clopidogrel	28 (14.0)	8 (8.0)	20 (20.0)	0.01
Prasugrel	50 (25.0)	29 (29.0)	21 (21.0)	0.19
Protamine	1 (0.5)	1 (1.0)	0 (0.0)	1.00
None	121 (60.5)	62 (62.0)	59 (59.0)	0.66
Bleeding outcomes				
Bleeding BARC ≥1 at discharge	55 (27.5)	28 (28)	27 (27)	0.85
BARC 1	30 (15.0)	16 (16.0)	14 (14.0)	0.69
BARC 2	25 (12.5)	12 (12.0)	13 (13.0)	0.81

Continuous variables are expressed as mean±SD, median [Q1-Q3]; categorical variables are expressed as absolute and relative frequencies.
AVK, vitamin K antagonist; BARC, Bleeding Academic Research Consortium; BMI, body mass index; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; DAPT, dual antiplatelet therapy; DOAC, direct oral anticoagulants; HBR, high bleeding risk.

Figure 1 "The Secret" is based on one of the miracles of Jesus recorded in the synoptic gospels (Matthew 9:20–22, Mark 5:25–34, Luke 8:43–48) as "Jesus healing the bleeding woman". This is depicted in the Catacombs of Marcellinus and Peter in Rome, Italy. Unknown author, marked in the public domain, details on Wikimedia Commons.

found in 52.5% (n=105) of patients and its prevalence did not significantly differ between the groups (S-group: 46% (n=46) vs C-group: 59% (n=59), p=0.08). Dyslipidaemia was more prevalent in the C-group (62% (n=62)) than in the S-group (47% (n=47), p=0.03). Overall, 21% (n=48) of patients were on dual antiplatelet therapy before coronary angiography (S-group: 20% (n=20) vs C-group: 23% (n=23), p=0.49). Oral anticoagulation as standalone therapy was taken by 6% (n=6) in the S-group and 11% (n=11) in the C-group (p=0.21). No patient was on triple therapy. HBR-ARC minor and major bleeding criteria were evenly distributed across the two groups (S-group: 20% (n=20) vs C-group: 25% (n=25), p=0.40). Three percent (n=3) of patients in the C-group presented with definite thrombocytopenia compared with none in the S-group (p=0.08).

Overall, 75% (n=150) of patients believed in the healing power of the blood charm and there was no statistical difference with regard to that belief among the groups (S-group: 73% (n=73) vs C-group: 77% (n=77), p=0.51)).

There was a trend towards a more frequent use of the radial access in the C-group (64% (n=64) vs 51% (n=51), p=0.06). The concomitant periprocedural administration of aspirin and heparin was more frequent in the C-group (17% (n=17)) than in the S-group (7% (n=7)) (p=0.03). The periprocedural administration of other drugs was evenly distributed. Some 37% (n=37) of patients in the S-group and 41% (n=41) in the C-group received loading with a P2Y12 inhibitor after percutaneous coronary interventions (p=0.97).

The primary endpoint occurred in 27.5% (n=55) of patients. In the S-group 28% of patients (n=28) presented with BARC ≥1 bleeding whereas in the control group the

rate of bleeding was 27% (n=27) (p=0.85). No major bleeding (BARC ≥3) occurred in either group.

DISCUSSION

"The Secret" is part of a magical conception of medicine. It is a remnant of the medical practices of the Middle Ages, when medicine was reduced to its simplest expression and was practiced by monk-practitioners, or sorcerers, based on one of the miracles reported in the synoptic gospels as "Jesus healing the bleeding woman" or the *haimorroïs* (Matthew 9:20–22, Mark 5:25–34, Luke 8:43–48) (Figure 1). General knowledge about medicine and science has advanced beyond the magical thinking that dominated earlier millennia.[9] However, recent enthusiasm for "alternative" medicines and healers, which is particularly intense on social media since the last COVID-19 pandemic started,[10] or the techno-optimism towards global warming,[11] are proof of persistent magical thinking among the general public.

As we live in a society where a significant proportion of individuals believe in "The Secret" or the prevention of bleeding, we tested it empirically. In doing so, the main strengths of the study were to scientifically evaluate a popular "belief" using "Secret Makers", randomisation, double blinding, and a significant sample size to permit the detection of differences between both groups. Indeed, the realm of belief is often a place that is not accessible to the scientific community and rigorous testing. Without the free, enthusiastic and unconditional help of blinded "Secret Makers" patients and caregivers, this study would be of little value. Yet, the study showed that although most participants believed that "The Secret" would be beneficial, there was no effect – positive or negative – on bleeding.

Although this outcome was expected by most physicians, a substantial proportion of patients ask for such an approach. This apparent discrepancy between the measured effects on bleeding and patient demands touches on an aspect that was not addressed by this study but which can be understood as stress management and well-being. The reduction of stress in the patient who has used a "Secret Maker" has been considered after burns.[2] As such, "The Secret" might allow some neuropsychological conditioning and act as a placebo as do other beliefs or biofeedback techniques.

Study limitations

This study is limited in size and is a single-centre study with homogenous practices among operators. Despite randomisation, there is also a trend for more patients in the control group to be treated by the radial approach. Since radial access has been shown to decrease major vascular complications and major bleeding, we cannot exclude the possibility that this difference between the two groups may have contributed to a bias and reduced the strength of the analysis.

CONCLUSION

"The Secret" is not effective in preventing post-interventional bleeding after percutaneous coronary interventions.

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Competing interests None declared.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval This study involves human participants and was approved by Lausanne CHCER-VD 2021-01877. Participants gave informed consent to participate in the study before taking part.

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REFERENCES

1 Zollman C, Vickers A. What is complementary medicine? *BMJ* 1999;319:693–6.
2 Kasser S, Applegate LA, Hirt-Burri N, *et al*. Acceptation of folk medicine and its "secrets" in a Swiss burn centre. *Ann Burns Fire Disasters* 2019;32:227–33.
3 Magali J. Chapter 1. In: *Nouveau guide des guérisseurs de Suisse romande*. 3rd edition. Switzerland: Favre, 2019.
4 Murali S, Vogrin S, Noaman S, *et al*. Bleeding severity in percutaneous coronary intervention (PCI) and its impact on short-term clinical outcomes. *J Clin Med* 2020;9:1426.
5 Amin AP, Miller S, Rahn B, *et al*. Reversing the "risk-treatment paradox" of bleeding in patients undergoing percutaneous coronary intervention: risk-concordant use of bleeding avoidance strategies Is associated with reduced bleeding and lower costs. *J Am Heart Assoc* 2018;7:e008551.
6 Delaloye G. Guérisseur d'âmes et de corps, thérapeute en soins énergétiques, faiseur de secrets, magnétiseur, masseur détente et santé, 2022. Available: http://www.gedelaloye.ch/ [Accessed 25 Jul 2022].
7 Urban P, Mehran R, Colleran R, *et al*. Defining high bleeding risk in patients undergoing percutaneous coronary intervention. *Circulation* 2019;140:240–61.
8 Cao D, Mehran R, Dangas G, *et al*. Validation of the Academic Research Consortium high bleeding risk definition in contemporary PCI patients. *J Am Coll Cardiol* 2020;75:2711–22.
9 Magner LN, Kim OJ. Chapter 6. In: *A history of medicine*. 3rd edition. Boca Raton: CRC Press, 2017.
10 González-Padilla DA, Tortolero-Blanco L. Social media influence in the COVID-19 pandemic. *Int Braz J Urol* 2020;46:120–4.
11 Smil V. Beyond magical thinking: time to get real on climate change. Yale E360. Available: https://e360.yale.edu/features/beyond-magical-thinking-time-to-get-real-about-climate-change [Accessed 14 Sep 2022].