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A single centre cohort study

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CONFLICTS OF INTEREST
none declared.

PRESENTATIONS OF PRELIMINARY DATA
none declared.

SUMMARY Patients undergoing (high-risk) surgery are at risk for complications and mortality. Recent studies show evidence for disparities in clinical outcomes between patients with ethnic minority and majority backgrounds. This study aimed to evaluate presumed differences in peri-operative safety between non-western minority and Dutch majority patients in a non-university hospital (621 beds) serving the Rotterdam region covering an ethnic divers population.

In a cohort study 2,466 patients with major abdominal or vascular surgery (mortality risk>1%) in 2012 and 2013 were included. Country of birth was used to determine patients' nationalities. Patient and surgery characteristics were collected to compare non-western and Dutch patient groups after abdominal or vascular surgery. Safety outcomes included safety indicators of the Dutch guidelines for peri-operative patient care (developed by The Dutch Society of Anesthesiology and The Dutch Surgical Society), completed with mortality rate, complication rate, and length of stay.

In total, 2,060 (84%) Dutch majority and 406 (16%) non-western minority patients could be identified. Age, social economical status and ASA-class were higher in the Dutch group. Most safety indicators showed no differences between both patient groups. Taking the differences in patient and surgery characteristics into account, non-western patients received antibiotics more often on time pre-operatively (81.4% vs. 65.8%, respectively, P<.001). Non-western patients also showed a lower complication rate (7.9% vs. 12.9%, respectively, P<.004).

In conclusion, no disparities in peri-operative patient safety were found in disadvantage of non-western patients. Moreover, some safety outcomes were even better. More research is needed to study these differences so all patients can profit from lower complication risks.

Keywords: Anaesthesia ethnicity, patient safety, peri-operative, surgery.

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HIGHLIGHTS

- No disparities in peri-operative patient safety were found in disadvantage of non-western patients in the hospital under study.
- Patients from the non-western ethnic group showed lower complication risks compared to the Dutch group in the hospital under study.
- Non-western patients received antibiotics more often on time compared to the Dutch patients in the hospital under study.
- More insight is needed in what factors influence these differences so all patients can profit from lower complication risks.

SAMENVATTING Patiënten die een (hoog risico) operatie ondergaan, lopen risico op complicaties en mortaliteit. Recente studies tonen bewijs voor verschillen in klinische uitkomsten tussen patiënten van niet-westerse afkomst en autochtone patiënten. Deze studie evalueert mogelijke verschillen in perioperatieve veiligheid tussen patiënten van niet-westerse afkomst en autochtone Nederlandse patiënten in een niet-universitair ziekenhuis (621 bedden) in de regio Rotterdam.

In deze cohortstudie zijn 2.466 patiënten met een hoog risico abdominale of vaatchirurgische operatie (mortaliteitsrisico>1%) tussen 1 januari 2012 en 1 januari 2014 geïncludeerd. Patiënt- en operatiekenmerken zijn postoperatief verzameld om patiënten uit beide etnische groepen te vergelijken. Veiligheidsindicatoren van de Nederlandse richtlijnen voor perioperatieve patiëntenzorg (ontwikkeld door de Nederlandse Vereniging voor Anesthesiologie en de Nederlandse Vereniging voor Chirurgie), aangevuld met sterftecijfers, complicaties, wondinfecties en verblijfsduur, zijn als uitkomstmaten gebruikt.

Van de geïncludeerde patiënten had 84% een autochtoon Nederlandse afkomst en 16% een niet-westerse afkomst. Leeftijd, sociaal economische status en ASA-klasse waren hoger in de autochtoon Nederlandse groep. Voor de meeste veiligheidsindicatoren bleek er geen verschil tussen beide patiëntengroepen. Bij relatief meer niet-westerse patiënten werd de preoperatieve antibiotica tijdig toegediend dan bij autochtoon Nederlandse patiënten (respectievelijk 81,4% versus 65,8%, P<.001), rekening houdend met de verschillen in patiënt- en operatiekenmerken. Ook kwamen complicaties relatief minder vaak voor bij niet-westerse patiënten (respectievelijk 7,9% versus 12,9%, P<.01).

Concluderend zijn er geen verschillen in perioperatieve patiëntveiligheid gevonden in het nadeel van patiënten met een niet-westerse achtergrond. Sommige bevindingen bleken zelfs gunstiger voor de niet-westerse patiëntengroep. Meer onderzoek is nodig om deze verschillen te bestuderen, zodat de veiligheid van hoog risico operaties voor alle patiënten kan verbeteren.

Keywords: Anesthesie, chirurgie, etniciteit, patiëntveiligheid, perioperatief.

HIGHLIGHTS

- Er is geen negatief effect van etniciteit gevonden voor niet-westerse patiënten op de veiligheid van de perioperatieve zorg in het onderzochte ziekenhuis.
- Patiënten met een niet-westerse afkomst hebben een lager risico op postoperatieve complicaties vergeleken met autochtone Nederlandse patiënten in dit ziekenhuis.
- Bij patiënten met een niet-westerse afkomst wordt vaker tijdig preoperatief antibiotica toegediend dan bij autochtone Nederlandse patiënten in het onderzochte ziekenhuis.
- Beter inzicht in de factoren van invloed op deze verschillen is nodig om de zorg te verbeteren voor alle operatiepatiënten die een hoog risico operatie ondergaan.

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Introduction

There is increasing evidence that the non-western minority patient group is at higher risk for mortality and complications during peri-operative care, compared to the Dutch majority patients group [1-3]. With an estimated volume of surgery of 234 million, resulting in 7 million complications and 1 million deaths worldwide every year [4-6], there is room for improvement of peri-operative patient safety, especially in non-western minority groups. Safety in surgery could increase by introducing checklists [5, 7] and guidelines (a consensus statement for anaesthesia practice to enhance recovery after surgery (ERAS)) [8, 9]. The World Health Organization (WHO) estimated that the implementation of the WHO checklist could save around 500,000 lives annually worldwide [4].
About 1.2 million operations are performed annually in the Netherlands [10]. In response to the many shortcomings in peri-operative safety reported by the Dutch healthcare inspectorate [11-13], national peri-operative safety guidelines have been developed to improve peri-operative care [14-16]. The introduction of these guidelines is expected to improve safety and lead to better clinical outcomes. However, the reduction of mortality and morbidity depends on checklist compliance [17-19].
The Dutch peri-operative safety guidelines do not contain specific recommendations for the care of non-western minority patients. For example, the stop moments (activities needed to check whether all conditions for safe surgery have been met) might require specific attention for non-western minority patients because of possible barriers, such as language problems. But also physiological, genetic (cardiovascular risk factors in African Americans), cultural (belief in superior surgical results), understanding and religious aspects could lead to a higher risk of peri-operative incidents [1]. In the present study we investigated whether peri-operative patient safety differs between Dutch majority and non-western minority surgical patients in a Dutch hospital located in a region where the population consists of 37% non-western minorities [20]. To measure patient safety, we used the patient safety performance indicators that were developed together with the national Dutch guidelines [21], supplemented with other safety outcomes such as complication rates, mortality rates and length of stay.

Methods

Patient population

This cohort study was conducted in a Dutch teaching hospital, located in the city of Rotterdam, with 621 beds and about 34,000 annual admissions. All adult patients (age ≥ 18 years) admitted between 1-1-2012 and 1-1-2014 for elective major abdominal, vascular or general surgery with a mortality risk > 1%, with a length of hospital stay ≥ 24 hours, were subject to inclusion [22]. The included patients were allocated to a non-western minority group or a Dutch majority group (definitions see below). Patients admitted for acute surgery (i.e. within 24 hours after admission), thoracic surgery and transplantation surgery, as well as western minority patients, were excluded.

Definition and determination of ethnicity

Country of birth, used to determine patients ethnicity, was recorded from the patients' passports on the day of admission. Patients were categorized as Dutch majority patients (further: Dutch patients), western patients or non-western minority patients (further: non-western patients) or 'unknown', using the definition of the Dutch Center of Statistics [23]. The category 'non-western' patients includes persons with a Turkish, African, Asian and Latin-American background, following the definition and classification of the population with a foreign background in the Netherlands (Statistics Netherlands (CBS) [24]. Based on their social and economic position in Dutch society, patients with a Japanese and Indonesian background were classified as western. Patients not born in the Netherlands and not born in a 'non-western country' were classified as born in a non-Dutch western country and were subsequently excluded [23-25].
Patients' ethnicity was identified independently by two reviewers (GB and GA) based on country of birth. Second generation non-western patients were identified by searching for non-western surnames in combination with the Netherlands as country of birth. Other studies showed that this method of identifying patients' origins has been proven to be valid and useful [26, 27]. In order to verify their origin, a sample of 5% of the patients originally categorized as Dutch majority patients, were contacted by telephone to check whether second generation non-western patients (with Dutch surnames) were incorrectly categorized as Dutch majority patients. This resulted in an error margin of 4%, indicating a sensitivity of 94-100% and a specificity of 95-100%, which is in line with previous studies [26, 27].

Patient and surgery characteristics
To account for possible case mix differences, data on age, sex, socio-economic status (SES) and American Society of Anaesthesiologists (ASA) class data were collected. To calculate the age, the date of birth was subtracted from the date of operation. SES scores were based on the postal area codes of patients and calculations of The Netherlands Institute for Social Research (Sociaal Cultureel Planbureau-SCP) [28]. The SES of a postal area code is calculated from a number of characteristics of the people living in that area: educational backgrounds, incomes, and positions in the labour market. Mean SES score for the Netherlands in 2010 was 0.17. (range -5.08 to 2.83). The patients' physical status was judged and scored pre-operatively by an anaesthesiologist using the ASA classification. Birth date, gender, date of operation and ASA class were retrieved from the hospital's database.

We defined six types of surgery: Intestinal, cholecystectomy, gastric, mixed abdominal, peripheral vascular and aortic surgery. Renal, esophagus, liver, spleen and pancreatic surgical interventions (removal or tumour resection in or around these organs) were put together in the category 'mixed abdominal' because of the low frequency of these interventions. Abdominal and vascular surgery were defined as separate groups. The duration of surgery was calculated by distracting starting time from end time.

Patient safety indicators measuring safety performance and safety outcome
An existing set of ten patient safety indicators was used (Table 1, indicators 1-10) [29]. Eight safety indicators covered the safety performance of the entire peri-operative care process, including the timely administration of antibiotic prophylaxis (within 15-60 minutes before incision), whereas two indicators measured outcome in terms of wound infections and mortality. Two

	Indicators	Type of indicator	Registered by:
1	Pre-operative risk management [a]	Process	Anaesthesiologist and surgeon
2	Planning (not recorded) [a]	Process	Anaesthesiologist and surgeon
3	Check of the current situation [a]	Process	Surgeon/ward nurse and holding nurse
4	Time-out before the operation [a]	Process	Surgeon
5	Sign-out after the operation [a]	Process	Surgeon
6	Discharge from recovery [a]	Process	Recovery nurse and ward nurse
7	Discharge from hospital [a] (not recorded)	Process	Surgeon
8	Timely administration of antibiotic prophylaxes [a]	Process	Holding nurse or anaesthesiologist
9	Post-operative wound infections [b]	Outcome	Hospital microbiologist, surgeon
10	Post-operative mortality [b]	Outcome	Surgeon
11	Post-operative complications [b]	Outcome	Surgeon
12	Length of hospital stay [b]	Outcome	Hospital registration department

Table 1. Patient safety indicators measuring safety performance and outcome

[a] Indicator derived from the IGZ (Dutch Health Care Inspectorate) report [11-13] and the Dutch peri-operative safety guidelines[14-16]
[b] Extra added to the set of safety measures[29]

other outcome indicators were added in this study, measuring complications and length of stay (Table 1; indicators 11, 12).

Mortality was defined as death within 30 days after the operation. Complications were defined as unintentional and undesirable events during or following surgical treatment in the hospital, in such a way that either adjustment of the patients' treatment was necessary or that harm was irreversible [30]. The Clavien-Dindo classification [31, 32] was used to classify complications. Length of stay was defined as the length of an inpatient episode of care, calculated from the day of admission to the day of discharge, and based on the number of nights spent in hospital [33].

Statistical analyses

A priori power calculation revealed that 400 patients undergoing surgery were needed for each group (Dutch patients and non-western patients) to be able to detect differences of 10% or more in safety performance indicators or safety outcomes, with a power of at least 80% and precision of 7.1% (half-width of the 95%-CI for the difference). These criteria were based on a hypothetical (worse case) difference of 50% vs. 60% and the standard error based on a relative frequency of 50% because then the variance is largest. Descriptive analyses were performed using means and standard deviation for continuous variables (e.g. age and SES) and percentages for dichotomous or categorical variables (sex, ASA class). Means (and if applicable standard deviations or range) and percentages were computed for patient characteristics, surgery characteristics, and safety indicators. Differences at baseline were tested using T-test (two-sided) and Anova for age and SES and Chi-square test for sex and ASA. Length of stay was dichotomized in ≤ 3 days or > 3 days.

Regression analyses were used to test the effect of the potential confounding variables. Firstly, the raw Odds Ratio was calculated for the effect of country of birth on eight safety performance indicators and four safety outcomes. Subsequently, patient characteristics (age, sex, SES and ASA class (for regression analyses grouped into two categories class 1&2 and 3&4, class 5 did not appear), surgical characteristics (operation type, surgery duration) and safety indicators, were subsequently added in the regression analyses (denoted models 1, 2 and 3). For each safety outcome - complications, wound infection, length of stay and mortality - the effect of the safety outcome was subsequently tested after adjusting with the patient and surgery characteristics (denoted model 4). Sensitivity analyses were used to test the effect in abdominal and vascular subgroups.

All statistical analyses were conducted with SPSS (version 22) software for Windows.

This study was performed according to a research protocol that was developed before the application for a grant. The project description is available from the website of ZonMW [34], dossier number 80-82315-97-11100 and project number 1711030089. This work has been reported following the STROCSS-criteria [35]. Regarding criterion 4c: the research protocol was also registered in the Research Registry database in 2017 (www.researchregistry.com; number 2669), after data collection (registration is possible since 2015).

Results

Patient population

A total of 12,302 patients underwent surgery in 2012 and 2013. 9,724 patients were excluded because they did not meet the inclusion criteria. From the 2,578 selected patients undergoing high risk surgery, 96 patients were excluded because they came from (non-Dutch) Western countries and 16 patients because their country of birth could not be determined. Finally, 2,060 Dutch majority patients and 406 non-western patients were included in the study (Figure 1).

Origin of patients

Most patients (n=2,060; 83.6%) were categorized as Dutch patients, 370 patients (15.9%) were born in a non-western country, and 36 patients (1.5%) were second generation non-western patients.

Patient characteristics

Table 2 shows that majority and non-

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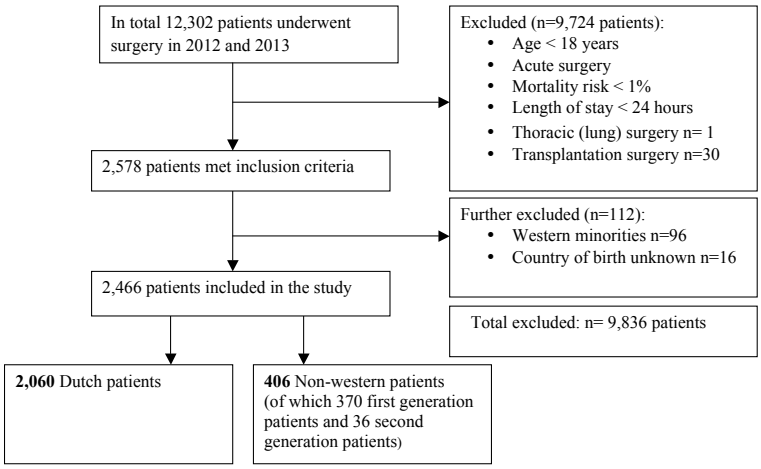

Figuur 1. Patient selection

western patient groups differ in background characteristics. The non-western group was significantly younger than the majority group (mean age 45.7 vs. 55.9 years, respectively P<.000), and consisted of significantly more female patients (79.9% vs. 60.3% P<.000). The SES scores for non-western patients were significantly lower compared to the majority group (-1.70 vs. -.50. P<.000). The percentage of ASA class 3-4 scores were significantly lower in non-western patients compared to the Dutch group (11.8% vs. 17.6% P<.005).

Surgery characteristics

Table 3 also shows significant differences between the Dutch and non-western group in types of surgery, except for cholecystectomy and mixed abdominal surgery. Non-western patients more often underwent abdominal surgery (91.1% vs. 74.6% P<.000) compared to the Dutch group, and less often vascular surgery (8.9% vs. 25.4% P<.000). Surgery took up significantly less time in non-western patients compared to Dutch patients (1:59^{hrs}[SD=0:59] vs. 2:22^{hrs}[SD=1:19] P<.000).

Safety performance indicators

There were no significant differences in six safety performance indicators between the non-western group patients and the Dutch patients group. The indicator 'pre-operative risk management' (98.7% vs. 100% P<.016) and the indicator 'timely antibiotic prophylaxis' (81.4% vs. 65.8% P<.002)

	Missing(n)		Dutch group	Non-western group	
			N =2060 (83.6%)	N = 406 (16.4%)	
Patient Characteristics					P-value[1]
Age		Mean {median} [sd]	55.9 {56} [17.0]	45.7 {43.5} [14.20]	.000
Sex		Female n (%)	1243 (60.3)	296 (72.9)	.000
SES[2]		Mean {median} [sd]	-.50 {-.34} [1.51]	-1.70 {-1.82} [1.65]	.000
		(%)1	350 (17.2)	92(23.0)	
ASA class[3]	(32)	(%)2	1327(65.2)	261(65.2)	.004
		(%)3	351(17.3)	47(11.8)	
		(%)4	6 (.3)	0	
Surgery Characteristics[4]					P-value
		Intestinal	301 (14.6)	36 (8.9)	.002
		Cholecystectomy	507 (24.6)	118 (29.1)	.061
Type of surgery[4] n (%)		Gastric	610 (29.6)	208 (51.2)	.000
		[5] Mixed abdominal	119 (5.7)	8 (2.0)	.760
		Peripheral vascular	265 (12.9)	17 (4.2)	.000
		Aortic	258 (12.5)	19 (4.7)	.000
Type of surgery[5] n (%)		Abdominal surgery	1537 (74,6%)	370 (91,1%)	.000
		Vascular surgery	523 (25,4%)	36 (8,9%)	.000
Duration of surgery		mean hr {median}[sd]	2:22 {1.57} [1:19]	1:59{1.47} [0:59]	.000

Table 2. Patient and Surgery Characteristics (N=2466)

1. P-value= Non-western compared to the Dutch group.[*sd*]=standard deviation.{median}=median
2. SES=Social Economic Status
3. For the statistical tests, four ASA classes were grouped into 2 categories, ASA class 1 & 2 and ASA class 3 & 4. ASA class significance was tested on difference between class 1 & 2 and 3& 4
4. Surgery Characteristics: Based on the data we defined 6 types of surgery: Intestinal, cholecystectomy, gastric, mixed abdominal, peripheral vascular and aortic surgery. Renal, esophagus, liver, spleen and pancreatic surgical interventions were put together in the category 'mixed abdominal' because of the low frequency of these procedures in all ethnic groups.
5. For clarity we presented two categories: abdominal and vascular surgery

	Missing(n)	Dutch group N=2060 (83.6%) (% pre-per or post operative agreement is executed)	Non-western group N=406 (16.4%) (% pre-per or post operative agreement is executed)	
Safety process indicators				P-value
[1]Preoperative risk	0	(98.7)	(100)	.015
[2]Planning	2466		NA	
[3] Check 3a nurse ward	96	(50.0)	(53.7)	.187
[3]Check 3b nurse holding	96	(44.3)	(45.6)	.658
[4]Time out	0	(97.6)	(98.0)	.720
[5]Sign out	[A]1248	(48.5)	(47.3)	.811
[6]Check 6a nurse recovery	96	(49.7)	(52.1)	.409
[6]Check 6b nurse ward	96	(36.3)	(39.3)	.279
[7]Discharge from hospital	2466		NA	
[8]Timely administration of antibiotics	1742	402 (65.8)	92 (81.4)	.001
Clinical outcomes				P-value
Complications 30 days		266 (12.9)	32 (7.9)	.004
Wound infections 30 days		65 (3.2)	8 (2.0)	.198
Length of stay		7.03[9,83]{3.00}	4.92[6,50]{3.00}	.058
Mortality 30 days[B]		33 (1.6)	3 (0.7)	.185

Table 3. Patient safety process and outcome indicators (N 2466)

P-value is non-western group compared to the Dutch group
NA = No data available in 2012 and 2013
A No data available for 2012
B Median length of stay was used as measure of distribution
C Expected count less than 5

Mean [sd]{Median[C] 3 days (50th quartile)}
Dutch (2 and 8 days = 25th and 75th quartile)
Non-western (2 and 4 days = 25th and 75th quartile)

differed significantly, with the latter in advantage for the non-western group (Table 3).

Safety outcome indicators
Complications within 30 days of operation occurred significantly less often in the non-western group compared to the Dutch group (7.9% vs. 12.9% P<.004), while also the odds ratio (Table 4) for complications appeared to be favorable for non-western patients (OR=.58 95% CI .39-.85 P<.01).

Effects of ethnicity on safety performance indicators and safety outcomes

In regression analyses (Table 5), after adjusting for patient and surgical characteristics, no effect was found of ethnicity on the safety performance indicators. The effect of ethnicity on the indicator timely administration of antibiotics and length of stay disappeared after adjusting for patient characteristics. Finally, the effect of ethnicity on complications remained significant in the adjusted model. Sensitivity analyses in subgroups show comparable results. We analyzed the effect of SES on complications in the Dutch group to determine the effect of SES on complications. The results did not show a statistically significant effect. The sensitivity analyses did not provide us with new information. These results are not shown in this article for reasons of clarity and readability.

Discussion

This explorative study showed no increased safety risk for non-western patients in high risk elective surgery in the hospital investigated. In contrast to what is usually found [1, 36], non-western patients showed fewer complications. In particular pre-operative antibiotics administration was more often on time in this group compared to the Dutch patients group.
Results showed various differences in background characteristics between both groups: the non-western group was younger, consisted of a higher number of female patients, had lower SES scores and more often lower ASA scores. Moreover, the surgical procedures were different, while also being characterized by shorter durations of the surgery (more abdominal surgery and less vascular surgery in non-western patients). These differences could have explained the positive results for the non-western patients group but were taken into account in further analyses.
The following factors possibly can partly explain the positive outcomes for non-western patients in this study:

1. High volume surgery experience with non-western patients. In this particular hospital, both professionals and patients made an effort to overcome their language barriers. This probably improved the content and understanding of preoperative information, while also speeding up the peri-operative process. Surgery was less often canceled because pa-

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tients had a better understanding of their pre-operative instructions for instance concerning the use of anticoagulation drugs or the sober policy.
2. Positive discrimination of the non-western group - for instance more attention and time needed for explanation may not be given to Dutch patients - and overestimation of health literacy skills in the Dutch group (Dutch patients could also actually need more time and attention for the explanation preceding surgery).
3. Background differences among ethnic groups, possibly originating from the pre-surgical decision process and perhaps caused by non-conscious bias in medical decision making [37]. To our opinion; possibly, general practitioners, surgeons or anesthesiologists may not give approval for high risk surgery because of their estimation that complications that might occur are generally higher in non-western patients. 4. Difference in timely presentation of the disease [38]. Non-western patients often presented later or not at all with their disease to the doctor [36, 38]. Such a longer delay in presentation usually resulted in worse clinical outcomes for them [39, 40]. but as a result of late presentation, surgical intervention is for some non-western patients probably not an option anymore and therefore lower risk surgery takes place in the non-western group. 5. There may be non-measured differences in biological (e.g. immune deficiency, malnutrition, tuberculosis etc), physiological (e.g. refugees from war zones), genetic, cultural, linguistic and religious factors possibly influencing postoperative morbidity and mortality. It is not unthinkable that these kinds of differences can also be found with respect to other hospitals in regions with a high representation of non-western people.

	Dutch group	Non-western group	OR[1]	P-value	95% CI
Type of surgery	n yes[2] (%) /n no[3] (%)	n yes[2] (%)/n no[3] (%)			
Abdominal surgery	199 (12.0) /1338 (88.0)	30 (8.1)/340 (91.9)	.59	.01	(.40- .89)
Vascular surgery	67(12.8) / 456 (87.2)	2 (5.6) / 34 (95.4)	.40	.22	(.09-1.71)
Total	266 (12.9) /1794 (87.1)	32 (7.9)/374 (92.1)	.58	.01	(.39- .85)

Table 4. Odds Ratio for complications: Non-western patients group compared to Dutch patients group

[1] OR = Odds Ratio: Non-western patients group compared to Dutch patient group
[2] n yes = amount of patients with a complication
[3] n no = amount of patients without a complication

In a recent Dutch multi-center study on hospital patient safety, an equal risk for adverse events was found for Dutch and non-western patient groups [41]. Differences in patient characteristics between Dutch and non-western patients in terms of low language proficiency, low health literacy, and a low educational level did not result in significantly increased risks of adverse events in Dutch hospitals. Instead, an effective response of healthcare providers to patients' needs was provided as an explanation in that particular study. In a recently published study it was concluded that equal access to the military healthcare system resulted in African-Americans having outcomes similar to whites. Disparities were however evident in California, especially among those without private insurance [42]. Therefore, access to healthcare is clearly an important factor for health care disparities.

Our findings must be interpreted in the light of the strengths and limitations of the present study. Firstly, our results cannot be generalized to all non-western patients in Dutch hospitals, since our study was conducted in one hospital located in a region with a relatively high percentage of patients from non-western backgrounds. Because of the relatively high referral rate of these types of patients, this particular hospital may have more knowledge of non-western patients and may be more experienced in working with them. Adequate and skilled language proficiency as well as cultural competence are both important factors to overcome health outcome disparities [43]. Secondly, methodological and statistical heterogeneity between groups and poor stratification of outcomes by race and ethnicity, can cause variations in results [2]. In our analyses we tried to take potential confounding factors into account. Thirdly, in ethnic disparity studies, poor and unstandardized identification methods to record country of birth increase the risk of misclassification.(1, 27) While country of birth is a useful indicator for a patient's ethnicity, it does not cover all dimensions of ethnicity, such as culture and ethnic identity [44]. In addition, although relatively few patients (8,9%) with a second generation non-western background were included in the non-western patients group, they could have contributed to the (positive) results of this group as they might differ from first generation non-western people [45]. However, the absolute number of 36 patients was too low to perform additional analyses. Fourthly, in our study the proportion of non-western patients in the study population was 16.5%, while the proportion of non-western patients in the hospital's region was 37%. It is remarkable that the non-western group was so much smaller than expected from the region numbers. To our opinion we had no or low risk of selection bias in our study, but we do not know whether there was any selection of patients prior to the surgery. Further consulting of annual reports of the regional hospitals did not reveal any information on this difference. The fact that patients might have opted for surgery in another hospital in the region could explain the smaller proportion of non-western patients in the participating hospital in our study. Additional analyses of the excluded patients revealed a relatively greater percentage of non-western patients (26.9% non-western vs. 19.4% Dutch) in need of acute surgery. The possibility that non-western patients have less access or poorer entrance to health services could have influenced the pre-surgical selection process; this may also have contributed to the differences found in the background characteristics of both groups [43]. In the Netherlands, the general practitioner acts as a gatekeeper, before hospital services are contacted. However, a study on the use of health care services by ethnic minorities in The Netherlands [46] reported that contact with other health care services without prior contacting a general practitioner was significantly less frequent for ethnic minorities compared to the Dutch population (except for Antilleans). Maybe people's perceptions of the quality of health services may have played a role; these perceptions could influence their

	[1]Raw OR scores			[2]Adjusted OR Model 1			[3]Adjusted OR Model 2			[4]Adjusted OR Model 3			[5]Adjusted OR Model 4		
	OR	95% CI for OR		OR	95% CI for OR		OR	95% CI for OR		OR	95% CI for OR		OR	95% CI for OR	
		Lower	Upper		Lower	Upper		Lower	Upper		Lower	Upper		Lower	Upper
Safety performance															
Preoperative risk	NR			NR			NR								
Check 3a nurse ward	1.17	.94	1.46	1.25	.99	1.58	1.26	.99	1.59	1.25	.99	1.58			
Check 3b nurse holding	1.07	.86	1.33	1.07	.85	1.36	1.07	.84	1.35	.75	.51	1.08			
Time out	1.19	.56	2.53	.99	.45	2.16	1.02	.47	2.22	1.01	.46	2.21			
Sign out	.88	.64	1.22	.89	.63	1.29	.88	.62	1.25	.89	.62	1.27			
Check 6a nurse recovery	1.21	.68	2.14	.96	.52	1.79	.88	.46	1.65	.81	.42	1.55			
Check 6b nurse ward	.98	.70	1.37	.86	.60	1.23	.82	.57	1.18	.80	.54	1.19			
Timely administration of antibiotics	2.20	1.32	3.64	1.73	1.00	3.00	1.75	.97	3.18	1.68	.93	3.05			
Safety outcomes															
Complications	.26	.09	.74	.32	.11	1.00	.29	.10	.96	.28	.08	.98	.28	.07	1.06
Wound infections	.47	.11	2.05	.81	.17	3.85	.60	.12	3.08	.65	.12	3.62	.76	.13	4.44
Length of stay	.53	.18	.54	.59	.27	1.16	.92	.34	2.48	.79	.29	2.20	.93	.32	2.72
Mortality	1.70	.21	13.53	0.56	.06	5.15	.44	.05	4.11	.32	.03	3.21	.32	.03	3.14

Table 5. The effect of 'ethnicity' on safety performance and safety outcomes, raw and adjusted Odds Ratios (OR)

Reference category: Dutch patients =1
Bold results: significance level P ≤ .05
1 The raw Odds Ratios (OR) for the effect of ethnicity on the registration of the safety indicators and health care outcomes.
2 Model 1, the effect of ethnicity adjusted for patient characteristics: age, sex, SES and ASA class were added into the regression model.
3 Model 2, the effect of ethnicity adjusted for surgical characteristics: operation type, surgery and anaesthesia duration were added into the regression model.
4 Model 3, the effect of ethnicity adjusted for the preceding safety indicators, e.g. preoperative risk; check 3a nurse ward; check 3b nurse holding; time out and sign out precede the check 6a at recovery.
5 Model 4, for each safety outcome - complications, wound infections, length of stay and mortality - the effect of the remaining safety outcomes was subsequently tested after adjusting for the patient characteristics and surgery characteristics
NR: Not reported due to skewed distribution

willingness to use services, since people are unwilling to use services that they perceive to be of poor quality or to be hostile to them [47]. Finally, a lot of effort was spent in determining the patients' ethnicity. However, there is a possibility that biomedical, cultural and ethnic differences exist among several ethnic groups which hinder the homogeneity and comparability of one non-western ethnic group. A valid determination of ethnicity is crucial to facilitate (large-scale international) biomedical ethnic research programmes [48, 49].

Based on the analyses of the non-western patients who were included in our study, we conclude that there is no increased safety risk for non-western patients in high risk elective surgery in the hospital investigated. These results are in line with another Dutch study [50] and may be explained by the effort of the hospital involved in improving peri-operative safety for their surgery patients with different ethnic backgrounds. Pre-hospital selection or a shift of non-western patients from elective to acute surgery could have muddled our results and conclusions. Adequate registration and reporting of country of birth and self-reported ethnicity of patients will improve the quality of ethnic studies. More insight is needed into the pre-surgical selection process to reduce differences and inequalities between ethnic patient groups and future studies should control for known pre-surgical selection factors. Moreover, more research is needed into factors that influence the comparability between ethnic groups to improve the quality of these studies. Further study, using qualitative methods, is needed to explore the perspectives of both patients and professionals on peri-operative patient safety, in order to reveal underlying mechanisms which explain the better safety outcomes for non-western patients and to get insight into contributing factors or explanatory mechanisms for the unexpected result of non-western patients receiving safer care.

Ethics approval

Ethics approval for this study (CMO registration nr 2011/318) was waived by the Ethical Committee (Commissie Mensgebonden Onderzoek region Arnhem-Nijmegen) Internal code 578, P.O. Box 9101, 6500 HB Nijmegen, the Netherlands (chairperson Dr. F. Huysmans) on 26-8-2011.

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