ORIGINAL ARTICLE

Efficacy of safety catheter devices in the prevention of occupational needlestick injuries: applied research in the Liguria Region (Italy)

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Keywords

Healthcare workers • Safety catheter device • Needlestick injuries

Summary

Healthcare workers who use or may be exposed to needles are at risk of needlestick injuries, which can lead to serious infections by bloodborne pathogens. These injuries can be avoided by eliminating the unnecessary use of needles and using safety devices. The present study was aimed at evaluating the impact of a safety-engineered device, with passive fully automatic needlestick protection, on the rate of needlestick injuries among healthcare workers.
The setting of the study was a network of five public healthcare institutions situated in a Northern Italian Region. Data on the type of device, the number of employees and the number of catheter devices used per year were collected through regular meetings with healthcare workers over a period of five years.
The most notable result of this study was the huge risk reduction associated with safety devices. Indeed, the risk of needlestick injuries due to conventional devices was found to be 25-fold higher than that observed for safety devices. However, it is noteworthy that a considerable part of this excess can be explained by the different background number of devices used.
Moreover, descriptive analysis suggested that individuals with a poor/moderate training level had a lower risk than those with good/high training, though the difference was not statistically significant.
In conclusion, there is convincing evidence of a causal connection between the introduction of safety devices and the reduction in needlestick injuries. This consideration should prompt the introduction of safety devices into daily clinical practice.

Introduction

A "sharp injury" is a penetrating stab wound caused by a needle or other sharp object, and may result in contact with blood or other body fluids. Needlestick injuries (NSIs) are among the most prevalent occupational accidents, with hollow-bore needles and disposable syringes as the primary sources of injury [1-3]. In hospitals, healthcare workers (HCWs), particularly nurses and physicians [4, 5], are at higher risk, but cleaning staff and other workers may also be exposed to NSIs, owing to the inappropriate disposal of sharp objects [6]. HCWs are at risk of sharp injuries and subsequent infection by more than 40 bloodborne pathogens or species [7]. The risk of HBV, HCV and HIV infection attributable to contact with infected blood has been estimated to be about 30.0%, 0.5%, and 0.3%, respectively. In Italy, the estimated yearly number of HCWs at risk of bloodborne infections is about 900,000, with nearly 96,000 NSIs [6, 8]. The importance of monitoring and preventing NSIs has been recognized in U.S. and European laws. In recent years, healthcare authorities, initially in the U.S. (Public Law, September 19, 2000), have focused their attention on identifying and utilizing proper medical devices to prevent NSIs and other sharp injuries in the workplace [9].
In Europe, Directive 2010/32/EU, approved on May 10, 2010, requires EU member states to implement a global strategy to prevent occupational exposure to bloodborne pathogens in healthcare settings as a result of needlestick and sharp injuries, including the adoption of devices incorporating safety features, on the basis of risk assessment [10].
The use of needlestick safety devices is an essential mean of protecting HCWs from NSIs [7, 11]. Several new devices are rapidly entering the market. However, not all devices are alike or equally effective. To significantly decrease the risk of injury, the design of safety devices should take into account specific features. In particular, they should be needle-less and work passively; if user activation is necessary, the safety feature should be activated by means of a one-handed technique and allow the worker's hands to remain behind the exposed sharp point. Moreover, they should be easy and practical; they should be safely and effectively usable for patient care and should possess ad-

ditional features, according to the American Nurses Association [12].
Several studies have reported that passive safety devices offer better protection against accidental NSIs than active devices [13-16]. However, certain authors have concluded that there is very low quality evidence that NSIs are significantly reduced by the using of safety devices [17].
In the present paper, we evaluated the impact of a safety-engineered device on the prevention of NSIs in five public healthcare institutions in a Northern Italian Region (Liguria). This study, conducted at the Protection and Prevention Department of San Martino Hospital in Genoa, was aimed at assessing whether a reduction in the number of NSIs caused by catheters could be observed as a consequence of the introduction of the Introcan Safety® IV Catheter Straight (ISCS IV). The ISCS IV is a safety device equipped with a fully automatic passive safety shield, and was investigated because it won the supply tender of Regione Liguria. This safety catheter requires no user activation; with regard to design and handling, it is identical to the conventional catheter [18, 19].
This device was phased in over the study period, starting with a replacement rate of 24% in 2006 and reaching full replacement in 2010 in almost all institutions, except for one in which only a very low replacement rate (30%) was reached.

Methods

The present study, designed as a quasi-experimental study, was performed in order to evaluate the impact of the ISCS IV (B. Braun Medical Inc., Germany) on the number of NSIs among HCWs over a five-year period (2006-2010). The ISCS IV was used for peripheral venipuncture and possessed a passive fully automatic needlestick protection. The setting of the study was a network of five public healthcare institutions located in Liguria, a Northern Region of Italy. The following healthcare institutions participated in the investigation: San Martino Hospital (SMH), Galliera Hospital (GH), Local Health Agency 1 (ASL 1), Local Health Agency 4 (ASL 4) and Local Health Agency 5 (ASL 5). SMH and GH are hospitals located in Genoa, while ASL 1, ASL 4 and ASL 5 represent local levels of the National Health Service, consisting of small-sized hospitals and outpatient departments situated in Imperia, Savona and La Spezia, respectively. To participate in the study, detailed information on the yearly number of NSIs and the type of device involved was required. Specifically, through regular meetings with HCWs, data were collected on the type of device, its classification as a conventional or safety intravenous catheter, the number of users and the number of catheter devices used per year by each institution.
As both conventional and safety devices were used concurrently during the study period, it was impossible to establish, even approximately, the yearly number of HCWs who used each type of catheter. We therefore assumed that the same number of HCWs were exposed to both catheters. The average number of yearly training hours in occupational health and safety per HCW in each institution was used as a measure of HCW expertise and knowledge of the proper use of catheters and the prevention of sharp injuries. In this respect, HCWs were classified as having poor/moderate or good/high-level training, with 2 hours per year being set as a threshold value.
The relative frequency of NSIs was the main response variable of this investigation. For this reason, the overall number of employees per year in each healthcare institution was assumed to be the number of person-years at risk of NSIs. Accordingly, the relative frequency was calculated as the ratio of the number of NSIs per person-year at risk, and indicated as the NSI rate (NSIR). The distribution of the NSIR was then analyzed according to the categories of each study characteristic or covariate (i.e., type of catheter, healthcare institution, calendar year, staff training level). In addition, 95% confidence limits (95% CL) were computed for each rate, assuming the number of NSIs as a Poisson random variable [20].
Calendar year was taken as a continuous covariate (i.e., linear time trend) in order to estimate the mean yearly percent variation (MPV). The joint effect of all covariates on NSIR was assessed by means of the Poisson regression model, and rate ratio was used as a measure of relative risk (RR). For each RR, 95% CL were also computed. Overall and covariate-specific statistical significance was assessed by means of the likelihood ratio test. A two-tailed P-value < 0.05 was considered significant. All analyses were performed by means of STATA [21]. The Poisson regression analysis was applied in order to estimate the relative risk between NSIR and corresponding 95% confidence limits (95% CL). All analyses were repeated on using the yearly number of catheters as a denominator (offset) of NSIR in the Poisson model [22].

Results

The analysis of NSIs was performed on HCWs from five different Italian healthcare institutions. Table I shows the main features of each institution. SMH and GH are hospitals with yearly catchment area populations of 1,500,000 and 100,000, respectively; while ASL 1, ASL 4 and ASL 5 include 3 to 4 small-sized hospitals, with yearly catchment area populations between 150,000 and 217,000.
Table II describes the distribution of the number of medical devices, person-years at risk, NSIs, and the relative frequency of NSIR. During the study, the total number of person-years at risk was 122,464, and 286 NSIs occurred. These data show an overall average NSIR of 23.4 per 10^4 person-years (95% CL = 20.8-26.2). The total number of catheter devices employed was 4,785,345, which corresponded to a yearly average of 39.1 devices per HCW. Table II also shows that the risk of NSIs due to conventional and safety catheters was 44.9 and 1.8, respectively, while the ratio of the number of conventional and safety catheters used per person-year was 51.8 and 26.4, respectively. Descriptive analysis revealed three risk levels: a lower

Tab. I. Main features of each healthcare institution.

Healthcare institution	Population[a]	Small-sized hospitals[b]	Bed availability[c]	Bed occupancy rate[d]	Admissions[e]
SMH	1,500.000	-	1500	86.74	63.35
GH	100,000	-	500	90.75	27.09
ASL 1	217,000	3	700	83.14	33.32
ASL 4	150,000	4	530	91.85	22.46
ASL 5	213,000	3	400	83.08	32.40

[a] Yearly population of catchment area
[b] Number of hospitals included in each ASLs
[c] Number of available hospital beds
[d] Percent ratio of the number of occupied hospital beds to the number of available beds per year
[e] Number of hospital admissions per year
SMH: San Martino Hospital; GH: Galliera Hospital; ASL: Local Health Agency

Tab. II. Risk of needlestick injuries.

	Number[a]	Person-years[b]	Ratio[c]	NSI[d]	NSIR[e]	95%CL[f]
Catheter device						
Conventional	3,170.695	61,232	51.8	275	44.9	39.9-50.5
Safety	1,614.650	61,232	26.4	11	1.8	1.0-3.2
Healthcare facilities						
GH	513,595	17,630	29.1	10	5.7	3.1-10.5
SMH	842,000	44,872	18.8	10	2.2	1.2-4.1
ASL 1	499,250	27,786	18.0	38	13.7	10.0-18.8
ASL 5	610,000	12,090	50.5	24	19.9	13.3-29.6
ASL 4	2,320.500	20,086	115.5	204	101.6	88.5-116.5
Staff training level						
Poor/moderate	609,250	24,054	25.3	46	19.1	14.3-25.5
Good/high	4,176.095	98,410	42.4	240	24.4	21.5-27.7
Calendar year						
2006	886,750	24,768	35.8	67	27.1	21.3-34.4
2007	908,900	24,220	37.5	64	26.4	20.7-33.8
2008	951,900	24,234	39.3	55	22.7	17.4-29.6
2009	1,022.895	24,526	41.7	65	26.5	20.8-33.8
2010	1,014.900	24,716	41.1	35	14.2	10.2-19.7
Whole sample	4,785.345	122,464	39.1	286	23.4	20.8-26.2

[a] Total number of catheter devices; [b] Employees considered at risk of needlestick injuries per year; [c] Ratio of total number of catheter devices to person-years at risk; [d] Number of needlestick injuries; [e] Occurrence rate of NSIs per 10,000 person-years; [f] 95% confidence limits for NSIR; SMH: San Martino Hospital; GH: Galliera Hospital; ASL: Local Health Agency

level (from 2.2 to 5.7 NSIR) for two hospitals (GH and SMH), an intermediate level (from 13.7 to 19.9 NSIR) for ASL 1 and ASL 5, and a higher level (101.6 NSIR) for ASL 4. Moreover, individuals with a poor/moderate and good/high training level had a NSIR of 19.1 and 24.4, respectively, while the NSIR calculated by calendar year showed a trend from 27.1 to 14.2.

Table III reports the result of the Poisson regression. The number of medical devices used during the study and the person-years at risk were considered in the model: the former as a log-transformed continuous covariate, the latter as an offset. A significant difference was found between RR calculated for conventional devices and that calculated for safety devices (RR = 12.50 *vs* RR = 1; P-value < 0.001).

All ASLs were found to be at higher risk of NSIs: these institutions showed RRs which were greater than 1.80 when the NSIR of GH was used as a reference. By contrast, from the comparison between the two hospitals (SMH *vs* GH), quite a small difference in risk (RR = 1.16; 95% CL = 0.42-3.24) was observed. In addition, a statistically significant two-fold increase in risk emerged when the overall rate of all ASLs was compared with the overall rate of the two hospitals (RR = 2.00; 95% CL = 1.01-3.92; P-value < 0.001) (data not shown). Regression analysis showed no significant difference in NSIR between the two training categories (good/high *vs* poor/moderate: RR = 0.88, 95% CL = 0.48-1.62). Lastly, regression modeling confirmed the downward trend obtained in the descriptive context, even though in a weaker and not statistically significant manner (RR = 0.95, 95% CL = 0.87-1.05). In practice, a 5% reduction in NSI risk was expected to occur in the various institutions during the study period (MPV -5%, 95% CL = -13.1% / +4.5%).

Tab. III. Effect of catheter type and staff training on needlestick injury occurrence estimated through the Poisson regression model.

	RR[a]	95%CL[b]	P-value
Constant[c]	7.2	2.5-20.2	-
Catheter device			< 0.001
Safety	1.00	Ref.[d]	
Conventional	12.50	5.56-25.00	
Healthcare facilities			0.236
GH	1.00	Ref.	
SMH	1.16	0.42-3.24	
ASL 1	1.83	0.80-4.21	
ASL 5	2.00	0.80-4.96	
ASL 4	3.19	1.17-8.67	
Staff training level			0.680
Poor/moderate	1.00	(Ref.)	
Good/high	0.88	0.48-1.62	
Calendar year			0.307
Linear trend	0.95	0.87-1.05	

[a] Needlestick injury occurrence rate ratio (relative risk) adjusted for the total number of catheter devices used; [b] 95% confidence limits for RR; [c] Baseline needlestick injury occurrence rate per 10,000 person-years at risk in all reference categories (year 2006) evaluated at the yearly median value (16,500) of catheter devices used; [d] Reference category. MH: San Martino Hospital; GH: Galliera Hospital; ASL: Local Health Agency

Discussion

Assessment of the risk of HCW exposure to biohazards is one of the main issues for occupational health professionals. The present investigation provides convincing evidence that the implementation of safety catheters is related to the reduced occurrence of NSIs, confirming reported previously results [14, 16, 23].

Through this non-concurrent prospective investigation, we assessed the impact of safety-engineered devices in five Ligurian public healthcare institutions, following a specific regional competitive tender that offered the opportunity to start adopting safety needles. During the study, a marked downward trend in NSIR by calendar year was observed. Specifically, the NSIR declined by approximately 47% from 2006 to 2010, which corresponds to a mean yearly reduction of about 9%. Over the same period, the number of medical devices employed per HCW increased by about 15%. Notably, conventional catheters were gradually replaced by safety catheters, starting from a replacement rate of about 24% in 2006, and reaching full replacement in 2010 in almost all healthcare institutions considered in the study, except for ASL 4, which only reached 30% replacement.

The most striking result of this study was the huge and statistically significant risk reduction associated with the use of safety devices. Indeed, the risk of NSIs due to conventional catheters was found to be 25-fold higher than that observed for ISCS IV. However, it is noteworthy that a fairly large portion of this excess can be explained by the different background number of devices used, in that the number of conventional catheters used per person-year was almost double the number of safety devices used.

Our analysis suggested that individuals with a poor/moderate training level had a lower NSIR than those with better training, though the difference was not statistically significant. This paradoxical result could also be explained by the large difference in the number of medical devices per person-year used in the study.

The present study certainly suffers from some epidemiological limitations, the main one being due to the study design itself; a substantial bias stems from the fact that the exposure-disease relationship was only estimated on the available lumped data (institution level) and could not be extended to each individual (HCW level). Indeed, we did not know whether a worker who reported a NSI had previously received adequate training in occupational safety, since we only knew the yearly average of training hours per worker in each institution. Unfortunately, this drawback, which is typical of this type of study design, can only be avoided by conducting epidemiological investigations based on individual records (i.e., case-control study).

A second limitation is the lack of information on healthcare personnel truly at risk of exposure to NSIs, in that the concept of person-years at risk included the time contributions of all employees (healthcare providers, administrative and maintenance workers), regardless of their actual jobs. All healthcare facilities belong to the same Regional Health Authority and, accordingly, are subject to the same health policy guidelines and service standards, which set the priorities in clinical care, define the quality of assistance, and establish the number of medical and allied health professionals engaged in the public health sector. Considering the moderate extension of the regional catchment area, which definitely reflects a small variability in the overall disease burden, it is reasonable and realistic to assume that the proportion of medical and healthcare professionals truly at risk of exposure to bloodborne pathogens was constant across institutions. However, this does not guarantee that all healthcare providers within a public institution have a homogeneous risk level. In this respect, a moderate degree of extra-Poisson variation or over-dispersion, due to the lack of some important covariates, was found. This was properly addressed by using a specific extension of the Poisson model, namely the negative binomial regression, which did not yield important changes.

Conclusions

This investigation revealed that the NSIR ratio associated with the use of the ISCS IV safety device was significantly lower than that of the traditional device. It can therefore be concluded that, despite the limitations of the investigation, there was a causal relationship between the introduction of the ISCS IV and the reduction in NSIs. In conclusion, convincing evidence in favor of the ISCS IV should prompt the introduction of this new catheter device into daily clinical practice, especially when a fair trade-off between clinical performance and HCW safety can be achieved.

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Authors' contributions

DS conceived, designed and coordinated the research, and participated in all stages of the work. MDG, RF, AP and LR collected data and performed the data quality control. RP and VF performed the statistical analyses. MM and LO evaluated the results and drafted the final manuscript. All Authors revised the manuscript and gave their contribution to improve the paper. All Authors read and approved the final manuscript.

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