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Radiology operators' preferences concerning the use of syringe-less Power Injectors during contrast-enhanced CT imaging procedures: a comparison between CT Exprès® and CT Motion™







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Radiology operators' preferences concerning the use of syringe-less Power Injectors during contrast-enhanced CT imaging procedures: a comparison between CT Exprès® and CT Motion™

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ABSTRACT EN

BACKGROUND

Syringe-less power injectors are technologies allowing simultaneous loading of two bottles to carry out multiple injections without reloading the contrast media after each contrast-enhanced CT imaging exam. Correct technologies evaluation models must consider the multidimensional characteristics of utility for operators and patients.

MATERIALS AND METHODS

The analysis was performed during two sequential observational periods, first using CT Exprès® and then CT Motion™ technology. By means of a 24-items questionnaire, value judgments (on a scale from 0 to 10) were collected from 9 operators on three aspects related to the use of a Chiara Martinotti. E-mail: chiara.martinotti@savestudi.it Thierry Roland. E-mail: thierry.roland@ch-nord-ardennes.fr Alexandre Muneaux. E-mail: al498@hotmail.fr Gregory Aernout. E-mail: gregory.aernout@ch-nord-ardennes.fr

ABSTRACT ITA

INTRODUZIONE

Gli iniettori automatici senza siringa sono tecnologie che consentono il caricamento simultaneo di due flaconi per eseguire iniezioni multiple senza ricaricare il mezzo di contrasto dopo ogni esame di imaging TC con mezzo di contrasto. Modelli corretti di valutazione delle tecnologie devono tener conto delle caratteristiche multidimensionali dell'utilità per operatori e pazienti.

MATERIALI E METODI

L'analisi è stata eseguita durante due periodi di osservazione sequenziali, prima utilizzando la tecnologia CT Exprès® e poi CT Motion™. Attraverso un questionario di 24 item sono stati raccolti giudizi di valore (su una scala da 0 a 10) da 9 operatori su tre aspetti legati all'uso di un iniet-

syringe-less injector: ease of use, safety of use, cleanliness and contrast wastage. For each item, the operators also expressed an estimate of the probability of occurrence of errors with potential practical consequences for the safety of the patient and / or for the efficiency of the procedure.

RESULTS

Respondents assigned high importance scores (≥8) for most of the items within all analysed domains (19 out of 22 rated items). Operators always expressed equal or higher preferences after operating on CT Exprès® vs CT Motion[™] injector. Specifically: 4 (out of 9) "ease of use" items, 5 (out of 9) "safety" items, 1 (out of 4) "cleanliness and wastage" items obtained much higher scores on CT Exprès®. For 70% of the items there is a non-zero to relevant probability of making mistakes if no technological solutions are offered by the injector to mitigate the risk.

CONCLUSIONS

The survey of preferences generates matrices of intrinsically coherent and correlated value judgments with the probabilities of negative events. Frequently the functionalities offered by the CT Exprès® injector determine greater desirability of innovative technological solutions for the 3 investigated domains. The presence of features that could mitigate the perceived risk of errors must be considered when evaluating power syringe-less injectors.

KEYWORDS

Syringe-less power injectors; CT; contrast media; health technology assessment; evaluation; ease of use; safety; cleanliness; wastage. tore senza siringa: facilità d'uso, sicurezza d'uso, pulizia e spreco del contrasto. Per ciascuna voce gli operatori hanno inoltre espresso una stima della probabilità di accadimento di errori con potenziali conseguenze pratiche per l'incolumità del paziente e/o per l'efficienza della procedura.

RISULTATI

Gli intervistati hanno assegnato punteggi di importanza elevata (≥8) per la maggior parte degli elementi all'interno di tutti i domini analizzati (19 su 22 elementi valutati). Gli operatori hanno sempre espresso preferenze uguali o superiori dopo aver operato su iniettore CT Exprès® vs CT Motion™. In particolare: 4 (su 9) voci "facilità d'uso", 5 (su 9) voci "sicurezza", 1 (su 4) voci "pulizia e spreco" hanno ottenuto punteggi molto più alti su CT Exprès®. Per il 70% delle voci c'è una probabilità di errore non nulla fino a rilevante se l'iniettore non offre soluzioni tecnologiche per mitigare il rischio.

CONCLUSIONI

L'indagine delle preferenze genera matrici di giudizi di valore intrinsecamente coerenti e correlati con le probabilità di eventi negativi. Frequentemente le funzionalità offerte dall'iniettore CT Exprès® determinano una maggiore desiderabilità di soluzioni tecnologiche innovative per i 3 domini studiati. La presenza di funzionalità che potrebbero mitigare il rischio percepito di errori deve essere considerata quando si valutano gli iniettori automatici di potenza senza siringa.

KEYWORDS

Iniettori senza siringa; TC; mezzi di contrasto; valutazione delle tecnologie sanitarie; valutazione; facilità d'uso; sicurezza; pulizia; spreco.



INTRODUCTION

The latest generation of power injection systems are multifunctional devices designed to complement Computed Tomography (CT) imaging procedures performed with contrast media (CM) infusion (contrast-enhanced CT or CECT) in order to increase patient safety and improve the diagnostic possibilities of the imaging modality.¹

Main advantages when using power injectors lie in the possibility of simplifying the injection steps (e.g., by easily adjusting the volume to be administered and the flow rate), improving the diagnostic effectiveness of the CT performance (e.g., by controlling contrast media dilution), optimising workflow (e.g., by minimising operational steps) and increasing patient and operator safety standards.²

Specifically, syringe-less power injectors are advanced injection technologies allowing simultaneous loading of two bottles to carry out multiple CECTs without reloading the CM after each exam. This translates into greater efficiency and less contrast wastage.²

The high standards of *performance* of the latest generation of power injectors have led to a steady increase of their use in hospitals and diagnostic centres. As a result, *procurement* departments are facing the issue of employing more effective, safe and efficient healthcare technologies in clinical practice, replacing those that are less effective, less safe and less efficient according to shared, monitorable and verifiable methods.³

It is appropriate that those in charge of purchasing decisions carry out multidimensional evaluations of the benefits that can be obtained, with a view to the medium and long term. Evaluations based only on cost-effectiveness indicators and focusing only on budgetary short-term aspects, entail the risk of interpreting the patients' wellbeing only partially and in a manner that contradicts the company or hospital's *mission*, both that of the public body and that of the private body.⁴

In business decisions it is therefore appropriate to adopt correct evaluation models for healthcare tech-

nologies, also considering the patients' and operators' preferences, and adopting criteria and methodologies based on *Health Technology Assessment* (HTA) principles to include the multidimensional characteristics of usefulness for both patients and operators.⁵

The Multi-Criteria Decision Analysis methods, for example, break down the object of the analysis into several simple factors, i.e., into criteria - which can then be grouped into broader sets called "dimensions" or "domains" - capable of providing a more comprehensive description. These criteria are then analysed separately and weighted among themselves, to arrive at a summary score indicating the value of the option being examined for those in charge of decision-making.⁶

The dimensions investigated include, among others: the technical relevance of the technology (which to some extent, depending on the degree of usability, determines the levels of diagnostic gain); the level of safety and tolerability of the procedure/technology; and the impact on the consumption of healthcare and non-healthcare resources, whether direct or indirect. These are dimensions which are not always covered by studies and surveys.²

Attaining high standards for these three dimensions often depends, rather than on the skills of the operator, on the degree of usability of the equipment and the technological solutions adopted to reduce the probability of error and/or waste, allowing for full control of the procedures. The degree of usability (and related testing) are critical components in human factors engineering. It is now well-established that, at every stage of the development of a technology (design, installation, maintenance, repair), users are a valuable quide in identifying the strengths and weaknesses of the interaction of a device with the users themselves. Usability testing⁷ serves to determine whether a given device can meet the users' needs and to assess whether a device may be the cause of errors in use (or even just be vulnerable to errors in use), with the possibility

of generating harm to users and patients. Verifying the ability of the equipment to respond comprehensively to the operators' and patients' needs is crucial, especially to achieve reassuring levels of safety for the operators and patients themselves.

MATERIALS AND METHODS

The comparative review examined various aspects of the use of two syringe-less systems (CT Exprès® by Bracco Injeneering S.A. and CT Motion™ by Ulrich Medical GmbH) for the automated administration of contrast media during CECT exams (abdomen and pelvis, chest, and brain CT performed using a Siemens Somatom go. CT scanner).

Since this study represents an exploratory research on the feasibility of collecting value judgements on certain factors and risk estimates of occurrence of certain phenomena, the data collection was carried out over a short period of time.

The survey was performed at Sedan Hospital (France) in May and June 2019 and was conducted by submitting a dedicated questionnaire (Appendix) to 9 operators (Radiology technicians).

All operators were expert in using CT Motion[™] equipment which had been running at the hospital since years, while CT Exprès[®] injector was installed for the purpose of this research and therefore an appropriate training was provided by Bracco representatives prior to the study.

The operators used both injectors during the study, in two sequential observational periods: 3 weeks for the CT Exprès® and for 4 weeks for the CT Motion™ injector. Each week and for each device, a contact person summarised the opinions expressed by his or her staff following the structure of an ad-hoc questionnaire. The expected number of imaging procedures was about 100 per week, conducted in both inpatient and outpatient setting. In total, about 600 procedures were carried out.

The questionnaire consisted of 24 questions defined with the aim to explore operators' preferences regard-

ing the importance, in their daily activities, of a series of *items*. The 24 *items* were meant to describe the desired situations/conditions to allow for the provision of effective and safe imaging services with minimum waste of production factors. For each of the *items* the respondent had to express, on a scale from 0 to 10, a value judgement concerning the importance he/she assigned to the situation/condition described by the *item*.

In addition, each situation/condition - except for two – was associated with a negative event. For each event, the respondent was asked to express a brief subjective estimate of the risk associated with the occurrence of the event: the estimate could have been based on his/ her own previous experience (probability) and/or on what observed by the operators during the week of activity (percentage). The probabilities (or percentages) were divided into five frequency classes: 0%; 10%–30%; 40%–60%; 60%–80%; and greater than 80%.

The 24 questions were divided into three specific sections referring to the following three dimensions of use:

- » a) ease of use (while performing the procedure), 10 questions
- » b) safety of use, 10 questions
- » c) cleanliness and contrast wastage reduction, 4 questions.

For the statistical analysis, average values were calculated for both absolute and percentage values which were then compared using simple differences. Given the small sample size, no statistical significance tests were performed.

RESULTS

ASPECTS RELATED TO EASE OF USE

Table 1 presents value judgements for the 10 criteria associated with "ease of use" domain:

- » only *item* "h" (*availability of a dilution feature*) did not receive enough responses
- » observers expressed high value of importance (mean value ≥ 8) for 8 of the remaining 9 items



TABLE 1

Value of importance (from 0 to 10) of aspects related to ease of use

		CT Exprè	€S®	CT Motio	n™	DELTA	TOTAL	
		N. questionnaires	Average	N. questionnaires	Average	Mean difference	N. questionnaires	Average
a)	Avoid waste of time time due to a complex installation of the daily set	3	9,0	4	9,0	0,0	7	9,0
b)	Have a dual interface that allows you to consult all injection parameters and avoid back and forth between the control and the scanner room	2	10,0	2	7,5	2,5	4	8,8
C)	Have a function that allows automatic adjustment of the flow rate for the different phases of a multiphase protocol	3	9,7	2	10,0	-0,3	5	9,8
d)	Have a feature that allows you to easily add phases to a selected protocol	3	9,7	3	9,7	0,0	6	9,7
e)	To be able to interrupt the injection procedure, pause the system and restart it quickly thanks to the simple management of the system itself	3	9,7	4	8,5	1,2	7	9,0
f)	Have a stopwatch configured in minutes	3	10,0	2	10,0	0,0	5	10,0
g)	Have information and alerts on available volumes to avoid the risk of interrupting the injection due to lack of contrast medium or physiological solution	3	9,7	4	9,5	0,2	7	9,6
h)	Have a function that allows the "dilution" of the contrast medium	n.d.	n.d.	1	0,0	n.d.	n.d.	n.d.
i)	Have an injector served by a wired power supply compared to a battery system	3	8,7	3	4,7	4,0	6	6,7
j)	Have a compact, handy and space-saving equipment	3	10,0	4,0	7,0	3,0	7,0	8,3

» only item "i" (availability of cabled system vs wireless system) received a mean value <8 (specifically, 6.7)</p>

For 3 *items* (out of the 8 high-value-rated *items*) observers expressed higher values when rating the experience on CT Exprès[®] and differences were particularly marked:

- » item b) availability of a double interface that allows the operator to consult all the injection parameters and avoid back and forth between the control and the scanner room was rated 10.0 on CT Exprès[®] and 7.5 on CT Motion[™] (difference in value of 2.5 points, equal to 25%)
- » item e) availability of a "stop and go" feature for the injection procedure was rated 9.7 on CT Exprès[®] and 8.5 on CT Motion[™] (difference in value of 1.2 points, equal to 12%)

» item j) availability of compact, handy and space-saving equipment was rated 10.0 on CT Exprès[®] and 7.0 on CT Motion[™] (difference in value of 3.0 points, equal to 30%)

To be noticed, also *item* i) *availability of cabled system vs wireless system* received higher value when rated on CT Exprès[®] vs CT Motion[™] (8.7 vs 4.7, a difference in value of 4.0 points equal to 46%). However, the condition itself received a mean value of 6.7 (<8).

For 5 out of 10 *items* the judgement was independent of the device being assessed (see values entered under "*mean difference*" column, *items* a), c), d), f) and g)): *avoiding waste of time due to a complex installation of the daily set*; *having a feature that allows for the automatic adjustment of flow rates during a multiphase protocol*; *possibility to easily add phases to a selected proto-*

col; having a stopwatch configured in minutes and having an alert on the residual volume of contrast before injecting were confirmed as factors that ensure ease of use. For these *items*, the scores exceeded 9.0 points and the difference between injectors was almost null.

Table 2 presents operators' estimates of the probability of errors during the contrast injection procedure. Only *item* h) *probability of making mistakes due to incomplete instructions from the system during the implementation of the "dilution" function* did not receive sufficient answers.

The set of responses can be divided into three groups. The first group corresponds to conditions of high confidence, where perceived risk is null (0%) regardless of the technology being used. The following *items* fall into this category:

- » item c) probability of making errors when configuring the different flow rates required during a multiphase protocol
- » item f) probability of making timing errors during a procedure when using seconds as a measure of time
- » item g) probability that the injection procedure is interrupted due to lack of contrast media or saline

The second group corresponds to conditions where perceived average risk is not null, between 1% and 9%. The following *items* fall into this category:

- » item b) probability of making errors when selecting the protocol (5%)
- item d) probability of making errors when adding steps to a protocol (3%)
- » item e) probability of making errors during the procedure when it is interrupted but cannot be resumed (6%)
- item i) probability of errors due to injection being stopped because of a problem with the power supply (3%)
- » item j) probability of problems occurring using heavy and bulky equipment (3%).

The third group corresponds to conditions associated with a relevant perceived risk (between 10% and 30%). Only 1 *item* falls into this category:

» item a) percentage of errors during the installation of the daily set (14%).

ASPECTS RELATED TO SAFETY OF USE

Table 3 presents value judgements assigned to 10 aspects related to safety of use of the medical device:

- » only *item* "h" (*availability of an integrated waste container*) did not receive enough responses
- » observers expressed high values of importance (mean value ≥ 8) for 8 of the remaining 9 items
- » only item "f" (availability of adapters for contrast media vials that allow for quick, sterile and clean instal-

TABLE 2

Probability of making mistakes while running the process

		N. questionnaires	% average
a)	Percentage of errors when installing the daily set	7	14%
b)	Probability of making mistakes when selecting the protocol	4	5%
C)	Probability of making mistakes when configuring the different flow rates required during a multiphase protocol	5	0%
d)	Probability of making mistakes by adding phases to a protocol	6	3%
e)	Probability of making mistakes during the procedure when it is interrupted but cannot be resumed	7	6%
f)	Probability of making timing errors during a procedure when using seconds as a measure of time	5	0%
g)	Probability that the injection procedure will be interrupted due to lack of contrast medium or physiological solution	7	0%
h)	Probability of making mistakes due to incomplete instructions from the system during the implementation of the "dilution" function	n.d.	n.d.
i)	Probability of errors due to an injection shutdown caused by a power issue	7	3%
j)	Probability of problems when using heavy and bulky equipment	7	3%



TABLE 3

Value of importance (from 0 to 10) of safety-related aspects

		CT Expré	€S®	CT Motio	n™	DELTA	TOTAL	
		N.		N.		Mean	Ν.	
		questionnaires	Average	questionnaires	Average	difference	questionnaires	Average
a)	Have an injector that allows, thanks to a double interface, to consult messages, injection parameters, pressure curve, etc. both in the control room and next to the patient	3	10,0	2	5,0	5,0	5	8,0
b)	Have consumables preventing risk of reuse, ensuring asepsis for the safety of the operator and the patient	3	10,0	3	9,3	0,7	6	9,7
c)	Being able to control the viscosity parameters of the contrast medium, the injection speed and the size of the needle	3	10,0	3	7,7	2,3	6	8,8
d)	Have a function that allows you to perform a vein test, reproducible on request	3	10,0	4	9,8	0,3	7	9,9
e)	Have an injector easy to setup and inizialize at the start of the day	3	9,7	4	9,8	-0,1	7	9,7
f)	Have adapters for contrast media vials which allow a quick, sterile and clean installation and prevent reuse	3	9,7	3	4,7	5,0	6	7,2
g)	Have disposable consumables that prevent reuse	3	9,7	4	8,3	1,4	7	8,9
h)	Have an injector that has an integrated waste bin	n.d.	n.d.	3	10,0	n.d.	n.d.	n.d.
i)	Have an injector incorporating a clamp system that prevents product flow until the patient is disconnected from the injector	3	9,7	3	7,0	2,7	6	8,3
j)	Have an injector equipped with software that allows you to monitor, in real time, the flow rate, the injection pressure of the contrast medium and that allows you to intervene quickly in the event of possible occlusion	2	10,0	4,0	9,5	0,5	6,0	9,7

lation and prevent reuse) received a mean value <8 (specifically, 7.2)

For 4 *items* (out of the 8 high-value-rated *items*) observers expressed higher values when rating the experience on CT Exprès[®] and differences were particularly marked. Rates associated with CT Exprès[®] always exceeded 9.7 points, while for CT Motion[™] were particularly low:

- » item a) having a dual interface allowing to consult messages, injection parameters, pressure curves, ... both in the control room and at the patient's side, was rated 10.0 on CT Exprès[®] and 5.0 on CT Motion[™] (difference in value of 5.0 points, equal to 50%)
- » item c) possibility to control contrast media viscosity, injection speed and needle size was rated 10.0 on CT Exprès[®] and 7.7 on CT Motion[™] (difference in value of 2.3 points, equal to 23%)
- » item g) availability of disposable consumables that prevent their reuse was rated 9.7 on CT Exprès[®] and 8.3 on CT Motion[™] (difference in value of 1.4 points, equal to 14%)
- » item i) the presence of a clamp system that prevents the product flow until the patient is disconnected from the injector was rated 9.7 on CT Exprès[®] and 7.0 on CT Motion[™] (difference in value of 5.0 points, equal to 28%)

To be noticed, also *item* f) *availability of adapters for contrast media vials that allow for quick, sterile and clean installation and prevent reuse* received higher value when rated on CT Exprès® vs CT Motion™ (9.7 vs 4.7, a difference in value of 5.0 points, equal to 50%). However, the condition itself received a mean value of 7.2 (<8).

For 4 *items* the judgement was almost independent of the device being assessed, even if differences between the two devices were not null and still always in favour of CT Exprès[®] (see values entered under *"mean difference"* column, *items* b), d), e) and j)): *having consumables preventing risk of reuse, ensuring asepsis for the safety of the operator and the patient; having a function to perform vein test, reproducible on request; having an injector easy to setup and initialize at the start of the day* and *possibility to monitor in real time pressure and flow rate graphs* were confirmed as factors that ensure safety of use. For these *items*, the scores always exceeded 9.7 points and the difference between injectors was between 0 and 7%.

Table 4 presents operators' estimates of the probability of errors with direct impact on the patients' and operators' safety during execution of the procedure. Only *item* h) *probability of contamination resulting from the use of injectors integrating a waste container* did not receive sufficient answers.

Again, the set of responses can be divided into three

groups. The following *items* fall into the first group, corresponding to a perceived risk equal to 0% regardless of the technology being used:

- » item f1) probability of errors when handling (installing/ removing) contrast media vials during the procedure
- » item f2) probability of contamination from repeated use of the same connector for different contrast media vials
- » item i) probability of contamination following the use of injectors without a flow blocking system

The following *items* fall into the second group, corresponding to an average perceived risk between 1% and 9%:

- item c) percentage of errors during assessment and combination of 3 parameters (contrast media viscosity, injection speed and needle size) (on average 7%)
- » item d) probability of errors during the injection procedure if a vein test is not available (on average 4%)
- » item e) probability of committing errors when loading consumables (on average 6%)

The following *items* fall into the third group, corresponding to an average perceived risk between 10% and 30%:

» item g) probability of contamination resulting from the re-use of disposable consumables, due to the absence of control measures preventing their re-use (on average 19%)

TABLE 4

Probability of making mistakes or contamination during the execution of the process

		N. Questionnaires	% average
C)	Percentage of errors made during the evaluation and the combination of these 3 parameters	6	7%
d)	Probability of making mistakes during the injection procedure	5	4%
e)	Probability of making mistakes when loading consumables	7	6%
f1)	Probability of making mistakes when handling (installing / removing) contrast media vials during the procedure	7	0%
f2)	Probability of contamination from repeated use of the same multi-use connector for different contrast media vials	7	0%
g)	Probability of contamination resulting from the re-use of disposable consumables, due to the absence of control measures preventing their re-use	7	19%
h)	Probability of contamination resulting from the use of injectors incorporating an external recovery tank	n.d.	n.d.
i)	Probability of contamination following the use of injectors without a flow blocking system	5	0%
j)	Probability of problems related to the use of an injector without a real-time monitoring system	7	14%



 item j) probability of problems arising from the use of an injector without a real-time monitoring system (on average 14%)

ASPECTS RELATED TO INJECTOR CLEANLINESS AND WASTAGE OF CONTRAST MEDIA

Table 5 presents value judgements assigned to 4 aspects related to device cleanliness and contrast media wastage, which have an immediate impact on the risk of contamination - with potential adverse effects on the patient - and the extent of potential economic damage:

- » observers expressed high values of importance (mean value ≥ 8) for 3 out of 4 items
- » only item "d" (availability of an injector that allows for the safe and temporary withdrawal of a vial of contrast media, at any time, with the possibility of re-installing it without loss of product, for a subsequent injection, with guaranteed sterility) received a mean value <8 (specifically, 7.7)

To be noticed, for *items* d) respondents provided very different scores depending on the injector in use, assigning only 6.3 points to CT Motion[™] (-35% compared to CT Exprès[®] which received 9.7 points).

Table 6 presents the ratings on the probability of occurrence of errors with direct impact on patient safety and unnecessary consumption of contrast media.

No *items* fall into the group corresponding to a perceived risk equal to 0%.

The following *item* fall into the group corresponding to an average perceived risk between 1% and 9%:

 item b) probability of making mistakes due to contamination (on average 3%)

The following *items* fall into the group corresponding to an average perceived risk between 10% and 30%:

 item a) percentage of errors made when contrast medium is poured onto the injector (on average 10%)

TABLE 5

Value of importance (from 0 to 10) of aspects related to cleanliness and wastage of contrast media

		CT Exprè	ès®	CT Motio	n™	DELTA	TOTAL	
		N. questionnaires	Average	N. questionnaires	Average	Mean difference	N. questionnaires	Average
a)	Have a clean injector and not have to clean up contrast media spills during your day	3	9,7	4	9,3	0,4	7	9,4
b)	Have an easy-to-clean injector that avoids the risk of contamination	3	9,7	4	9,5	0,2	7	9,6
c)	Have an injector that allows you to install small vials of contrast medium (towards the end of the day)	3	9,3	4	9,3	0,1	7	9,3
d)	Have an injector that allows you to withdraw a vial of contrast medium at any time and temporarily, in a safe way, having the possibility of reinstalling it without loss of product, for a subsequent injection, with the guarantee of sterility	3	9,7	4	6,3	3,4	7	7,7

TABLE 6

Probability of making mistakes and percentage of wastage due to contrast media spillage and vials handling

		N. questionnaires	% average
a)	Percentage of errors made when contrast medium is poured onto the injector	7	10%
b)	Probability of making mistakes due to contamination	6	3%
C)	Percentage of small vials of contrast medium used per day	6	7%
d)	Percentage of contrast medium becoming wastage	6	27%



 item d) percentage of contrast medium becoming wastage (on average 27%)

To be noticed, *item* c) *percentage of small vials of contrast medium used per day* is not considered for this analysis as it was meant to capture the use of small vials and not a % of risk.

DISCUSSION

It should be noted that the present study is an exploratory research on the feasibility of collecting operators' expectations and perceived dimensions of the problems associated with the use of syringe-less power injectors for the intravenous administration of contrast media during CT procedures.

For each dimension, the operators' expectations were collected through the expression of value judgements on a wide range of *items* concerning the importance of specific desired situations/conditions in the daily diagnostic activity and, consequently, the desirability of specific technological solutions in the equipment being used.

The operators were able to express their preferences consistently for 22 out of 24 *items*. Only 2 items were not rated, apparently showing no interest for the related condition:

- » for ease of use, item h) availability of a dilution feature
- » for safety of use, item h) availability of an injector with an integrated bin

We assume this may be due to the specific clinical practice.

High values of importance (average value ≥ 8) were assigned to most of the *items* (19 out of 22), thus indicating the relevance of the desired conditions listed for each analysed domain.

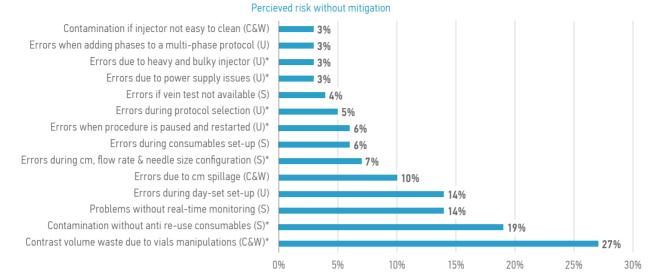
It seems fair to say that the operators' expectations - and therefore the judgement of the importance assigned to a specific functionality - were influenced by findings emerged during the observation period with injectors offering different capabilities. In general, it can be observed that the presence of superior functionality reinforced the desirability itself of the function.²

20 *items* (out of 22) were associated with a probability of making mistakes or occurrence of negative events. It can be assumed that the risk perceived by the operator, when no mitigating features are implemented to reduce that risk, is based on the operators' previous experience more than what observed during the limited period of the study.

Overall, results show average values between 0% and 30%. For 6 out of 20 *items* (equal to 30% of cases), estimated risk was null showing high confidence by the operator. Those cases seem to correspond to situations where operators' expertise and best practice can mitigate the risk. For 14 out of 20 *items* (equal to 70% of cases), estimated risk was not null (between 1% and 9%) or even relevant between 10% and 30% (Figure 1). Data therefore clearly indicate that there is a set of functions which need to be considered when evaluating the adoption of a syringe-less technology: the capability to offer specific functionalities could in fact potentially mitigate the risk of errors due to either specific patient clinical conditions or procedural complexities requiring a high level of attention from the operators.

We can anticipate that a possible line of future development of this analysis should be aimed at defining classes of possible practical consequences: these could range from impacts on organizational efficiency (waste of time, services delay, long waiting lists) to risks for the operators' and patients' health, to aggravation of the psychological patients distress and to higher costs due to consumables waste. In particular, the risks for patients' health could manifest themselves in a wide range of clinical consequences of different severity: from repetition of the procedure (exposing the patient to greater procedural risks and higher levels of radiation) to damage to the vessel wall: from dislocation of the catheter and vascular trauma (due to not-efficient control of contrast media pressure and flow rate) to the risk of injecting air into the patient's vessels (a potentially fatal embolism), and haematoma due to extrav-





(U)= easy of use; (S)= safety; (C&W)= cleanliness and wastage. *Corresponds to desired condition which received higher value on CT Exprès.

asation of the contrast media. Unsafe administration (e.g., mishandling of contrast media single-dose bottles or unintentional reuse of disposable consumables) could lead to infections (hepatitis B or C and bacterial infections) invading the blood stream.

Analysing each individual domains, we can highlight the following findings, among others.

ASPECTS RELATED TO EASE OF USE

As expected, Table 1 shows that operators judge of high importance most of the *items* in the analysed domain. Only the *item* concerning the availability of a *contrast dilution* feature did not receive enough responses – possibly because the set of imaging services carried out during the observation period were not requiring the need to dilute the contrast media with saline.

For 4 *items*, the experience on CT Exprès[®] injector led to higher value judgements of the related functionality vs CT Motion[™] (Figure 2, differentiating features related to ease of use). These features are clearly identifiable in:

- » item i) power supply (46% higher rating for CT Exprès®)
- » item j) footprint (30% higher rating for CT Exprès®)

- » item b) double interface, with same functionalities (25% higher rating for CT Exprès®)
- » item e) stop/pause/restart button (12% higher rating for CT Exprès[®])

The possibility of having an injector served by a wired power supply as opposed to a battery-powered system (*item* i)), which scored less than 8 points, was also marked by a large difference in value between CT Exprès® and CT Motion[™] (8.7 vs 4.7 respectively). This seems to suggest that operators - whose previous experience was with CT Motion[™] - when working with CT Exprès® emphasised the usefulness of a cabled system while when operating with CT Motion[™] - which in Sedan's experience is typically a battery-powered injector - they reduce their expectations and consequently their score.

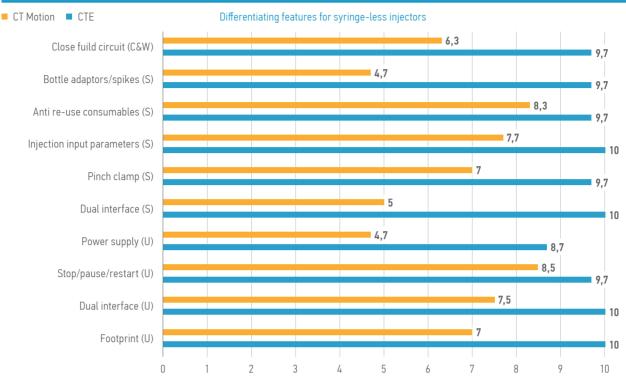
There is a set of functions that need to be considered when evaluating the adoption of a syringe-less technology in order to reduce the probability that negative events may occur:

- item a) if installation of the day set is too complex (on average 14%)
- » item e) if system cannot be paused and restarted when needed (on average 6%) *



FIGURE 2





(U)= easy of use; (S)= safety; (C&W)= cleanliness and wastage.

- » item b) if protocol selection is not available on both consoles (on average 5%) *
- » item d) if adding a new phase to a selected protocol is too complex (on average 3%)
- » item i) if a wired power supply is not available (on average 3%) *
- » item j) if injector is bulky and heavy (on average 3%) *

In relation to the above *items*, it is interesting to take note of some of the findings from the corresponding estimates of the probability of occurrence of negative events (Table 2). In four cases (*) with average perceived risk greater than 0%, (*items* b), e), i) and j)), the desirability of high-level technological solutions (Table 1) is marked by higher values when evaluated on CT Exprès[®] than on CT Motion[™]. The effectiveness of the functionalities offered by CT Exprès[®] was judged to have the potential to mitigate the risk of errors which may occur during the execution of the procedure.

ASPECTS RELATED TO SAFETY OF USE

As expected, Table 3 shows that operators judge of high importance most of the *items* in the analysed domain. Only for *item* h) related to the presence of an *integrated waste container* there were insufficient responses. The same applies to the corresponding *item* in Table 4. The absence of evaluations suggests that this equipment was not considered to be of immediate use for a correct procedure.

For 5 *items*, the experience on CT Exprès® injector led to higher value judgements of the related functionality vs CT Motion[™] (Figure 2, differentiating features related to safety of use). These features are clearly identifiable in:

- » item a) double interface, with same functionalities (50% higher rating for CT Exprès[®])
- » item f) bottle adapters (50% higher rating for CT Exprès®)
- » item i) pinch clamp (28% higher rating for CT Exprès®)



- » item c) control of input parameters: flow rates, contrast viscosity, needle size (23% higher rating for CT Exprès®)
- » item g) anti-re-use consumables (14% higher rating for CT Exprès[®])

The possibility of having *adapters* for the contrast media vials that prevent their reuse (*item* f)), which scored less than 8 points, was also marked by a large difference in value between CT Exprès[®] and CT Motion[™] (9.7 vs 4.7 respectively). This therefore confirms that the desirability of a feature emerges once tested in clinical practice.

These are the main factors that, when tested with the CT Exprès[®] injector, provide the operator with greater assurance of high level of control on the procedure and therefore high standards of safety. This reinforces the hypothesis that the presence of a wider range of equipment functionalities raises the desirability for greater operational potential, capable of cooperating effectively with the operator to avoid errors with an immediate impact on the safety of the patient and the operator herself.

Within the safety domain, data in Table 4 must be observed very carefully. For two *items* the probability of occurrence of negative events is relevant (between 10% and 30%):

- » item g) if consumables do not prevent their re-use (on average 19%) *
- » item j) if the injector does not offer real-time monitoring of pressure and flow rate curves (on average 15%)

And for three *items* is not null (between 1% and 9%):

- » item c) when user diligence is required to properly evaluate injection input parameters (on average 7%) *
- » item e) if injector set-up and loading of consumables is too complex (on average 6%)
- » item d) if there is not a dedicated test vein function (on average 4%)

The research reveals also for this domain a set of functions that should be kept in mind when evaluating the adoption of a syringe-less injector in order to reduce the probability of occurrence of negative events. Higher capabilities offered by a specific technology could have the potential to mitigate that risk: *item* c) and *item* g) in Table 3 show that features offered by CT Exprès® could result to be more effective than features offered by CT Motion[™] (*).

ASPECTS RELATED TO INJECTOR CLEANLINESS AND WASTAGE OF CONTRAST MEDIA

As expected, Table 5 shows that operators judge of high importance most of the *items* in the analysed domain, without showing significant differences between the injectors.

The one exception is represented by:

 item d) availability of a closed fluid circuit (35% higher rating on CT Exprès[®])

where the experience on CT Exprès® injector led to a much higher value judgements of the related functionality vs CT Motion[™] (Figure 2, differentiating features related to cleanliness and wastage).

Data in Table 6 confirm the need, also for this domain, to adopt equipment with technological solutions capable of mitigating the risk - which in this case translate into costs of lost material - and to guarantee high standards of hygiene by reducing the risks of contamination and easing cleaning operations.

For the following *items* the probability of occurrence of a negative event is greater than 0%:

- » item d) if the fluid circuit is not closed (thus leading to an average waste of contrast volume of 27%) *
- » item a) if contrast can easily pour onto the injector (on average 10%)
- » item b) if injector surface does not ease cleaning operations (on average 3%)

Table 6 shows that the *percentage of volume of contrast media becoming waste* assumes the relevant average value of 27%. (*) For the CT Exprès® injector the percentage was around 10% compared to 35% associated with the CT Motion[™] (Data not published in the table).

Further research is needed to overcome some inherent limitations of this work. It would be desirable to broaden the context (from single-site, French study to multi-centre, multi-national study) and the observational period (and therefore the sample volume), and to move from a survey based on a summary of the value judgements and probability estimates to a survey structured on the expression of judgements and specific negative events, procedure by procedure. Lastly, since the emergence of negative events of different nature may correspond to clinical consequences of varying severity, it would be appropriate to collect data on the extent of such effects on patients' and operators' safety, waste of resources (in terms of working time, exam repetition and contrast media usage), as well as on the possible need for clinical interventions.

CONCLUSIONS

Power injectors are medical devices intended for the automated intravenous administration of contrast media and saline during diagnostic imaging procedures, as an alternative to manual injection. They allow for the simple and accurate management of administration phases to obtain the greatest possible diagnostic gain ^{8,9}. Among those, syringe-less power injectors are technologies allowing simultaneous loading of two bottles to carry out multiple injections without reloading the contrast media after each exam:² on one hand they meet the *imaging* providers' needs for efficient work-flow and costs containment and, on the other hand, the operators' expectations for high hygiene and safety standards for themselves and for the patient.

The present study represents an exploratory research on the feasibility of collecting operators' expectations and perceived risks associated with the use of syringe-less CT injectors.

It is indeed advisable that - during procurement processes pertaining medical technologies - decision makers rely on multidimensional evaluation approaches based on *Health Technology Assessment* (HTA) principles and focused on the medium-long term benefits, for both patients and healthcare operators. Results clearly show that the functionalities offered by CT Exprès[®] always determined equal or higher scores when compared to those offered by CT Motion[®], in all domains analysed during this research: ease of use, safety of use, cleanliness and contrast wastage. In 45% of the cases (10 out of 22 *items*) the difference was significant (\geq 10%): an indicator that CT Exprès[®] features are perceived more in line with operators' expectations in terms of efficacy of technological solution implemented.

Regarding the emerging relationships between preferences and perceived probability of undesired events, it was found that in 70% of the cases the unavailability of risk-mitigating measures is associated with a non-null (between 1% and 9%) or even significant (between 10% and 30%) average probability of error. That perceived risk could potentially result in practical consequences for the safety of the patient and the operator, and/or for the efficiency of the procedure in terms of time and resources needed.

Those situations shall be taken as points of attention during the assessment of a syringe-less injector, as reflect conditions where operators do not only rely on their own expertise and best practice, rather they count on risk-mitigating solutions which should be offered by the technology itself. 7 out of 14 items (50%) for which a risk > 0% has been identified, correspond to desired conditions which received higher values when rated on CT Exprès® than on CT Motion®, thus indicating that CT Exprès® features could more effectively mitigate the risk of errors which may raise due to specific patient clinical conditions and/or procedural complexities requiring high level of attention by the operators.

In conclusion, the survey of preferences on CT Exprès® and CT Motion® syringe-less injectors generates evaluation matrices that are highly consistent and correlate with the probability of the occurrence of negative events during the entire workflow of a contrast-enhanced CT imaging protocol.

ETHICAL APPROVALS

The databases used did not contain a variable allowing for the individual identification of patients. The questionnaire did not involve sensitive data of the operators but only value judgments (on a scale from 0 to 10) were collected from 9 operators on three aspects related to the use of a syringe-less injector: ease of use, safety of use, cleanliness and contrast wastage. All results of the analyses provided by SAVEStudi to researchers were aggregated, indeed were not possible to assign, either directly or indirectly, to the individual operator.

DISCLOSURE

This project was conducted with the support of Bracco Injeneering S.A., Lausanne, Switzerland.

GLC, GMB, SDM, MCV and CM are employees of S.A.V.E. S.r.l and consultants for different pharmaceutical companies. All other authors report no other conflicts of interest in this work.

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APPENDIX

QUESTIONNAIRE

Merci d'avoir accepté de participer à cette étude visant à examiner les différents aspects (facilité d'utilisation, processus de travail et sécurité) de deux systèmes CT sans seringue.

Merci de prendre le temps de répondre à ce grand questionnaire qui nous permettra de recueillir vos impressions de manière structurée afin d'établir une analyse comparative équilibrée.

Répondre à cette enquête ne devrait vous prendre que 10 minutes. Veuillez noter que toutes les réponses aux questions resteront confidentielles et que l'analyse ne prendra aucune donnée personnelle en compte.

I. Facilité d'utilisation (processus de travail)

Sur une échelle allant de 0 à 10 (où 0 est la valeur minimale et 10 la valeur maximale), à quel point est-ce important pour vous, dans vos activités quotidiennes :

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QUESTIONNAIRE	
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10-30% 🗌

Sur une échelle allant de 0 à 10 (où 0 est la valeur minimale et 10 la valeur maximale), à quel point est-ce important pour vous, dans vos activités quotidiennes :

a) de disposer d'un injecteur propre et de ne pas avoir à nettoyer les écoulements de produit de contraste au cours de votre journée ?
 0
 1
 2
 3
 4
 5
 6
 7
 8
 9
 10
 Quel est le pourcentage d'erreurs commises lorsque du produit de contraste est renversé

dans l'injec	teur ? (Veuillez indi:	iquer une valeur en po	ourcentage)	
0% 🗆	10-30% 🗌	40-60% 🗌	60-80% 🗌	> 80% 🗌

b)	de dis	poser d'	un injecte	ur facile	à nettoye	r qui per	met d'év	iter les ris	ques de o	contamina	ation?
	0	1	2	3	4	5	6	7	8	9	10
	•	Quelle	est la pro	babilité d'	erreurs du	ies à la co	ntaminati	on ? (Veui	llez indiqu	er une val	eur en
		pource	entage)								

40-60% 🗌

60-80%

> 80%

c) de disposer d'un injecteur qui vous permet d'installer de petits flacons de produit de contraste (pour la fin de la journée)

- 7 0 1 3 4 5 6 8 9 10 2 Quel pourcentage de petites bouteilles utilisez-vous par jour (veuillez indiquer une valeur en pourcentage)? 0% 🗌 10-30% 🗌 40-60% 🗌 60-80% 🗌 > 80% 🗌
 - Si vous n'utilisez pas de petites bouteilles, quelles en sont les principales conséquences et comment sont-elles gérées habituellement ?
- d) de disposer d'un injecteur qui vous permet : de retirer à tout moment et provisoirement un flacon de produit de contraste de façon sécurisée, en ayant la possibilité de la réinstaller sans perte de Produit de Contraste pour une prochaine injection avec la garantie de stérilité contraste ?

0	1	2	3	4	5	6	7	8	9	10	
•	 Quel pourcentage de produit de contraste devient un déchet (veuillez indiquer une valeur en pourcentage) ? 										
	0% 🗆	10	-30% 🗆		40-60% 🗆	Ξ 6	60-80% 🗆		> 80% 🗆		



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