A Multifactorial Intervention for Reducing Catheter-Related Bacteremias on Intensive Care Units. Pilot Study Report

GOBIERNO DE ESPAÑA
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Plan de Calidad para el Sistema Nacional de Salud

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A Multifactorial Intervention for Reducing Catheter-Related Bacteremias on Intensive Care Units. Pilot Study Report.

This project is that of the contract signed between the Ministry of Health and Consumer Affairs and the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC).

(Pending review)

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1 Pilot Study Report

Since 1994, the Infectious Diseases Working Group (GETI) of the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC) has been studying the rate of device-related infections acquired in ICUs by way of the Changes in ICU-Acquired Infection Rates (ENVIN-UCI[1]) Study. Despite the surveillance concept being clearly implemented in a major number of Spain's ICUs, the evolution of the bacteremia rate related to the use of central venous catheters (CVCs) (including both primary as well as CVC-related bacteremias) given as incidence density (ID) (number of bacteremias per 1000 days CVC) has shown these infections to have remained somewhat the same throughout the years of this study, falling within the 5-7.9 episodes / 1000 days CVC. Although the lowest ID was recorded in 2006, the improvement is clearly below that found in U.S. ICU's over the past few years and also below those of different European countries taking part in the HELICS study[2,3].

Different initiatives based on multifactorial, training and prevention guide implementation strategies have shown themselves to be effective in reducing the CVC-related bacteremia rates. One of these studies, headed by Peter Pronovost and conducted at 103 ICUs in the State of Michigan has shown the possibility of reducing CVC-related bacteremia as being practically 0[4]. This intervention program came within the framework of a statewide safety initiative for patients admitted to ICUs, in which the main finding of the study was the impact this intervention had on the central venous catheter-related infection rate. This study was conducted throughout an 18-month period and was comprised of the following aspects:

- Implementation of a daily objectives sheet aimed at improving communications among ICU personnel and standardizing patient handling.
- Election at each unit of one physician and one nurse to be leaders in charge of disseminating the information and collecting the data necessary for the evaluation. This designation was prior to the implementation of the program, and they were trained for this mission.
- Implementation of the five procedures which have shown themselves to have a greater impact on reducing catheter-related infections (hand hygiene, use of maximum aseptic barriers during insertion, asepsis of the skin at the point of insertion with 2% chlorhexidine, avoiding the femoral access route and removing all unnecessary CVCs).
- Creation and use of a "Central line cart" and a Checklist for assuring adherence to and full compliance with the infection-control practices during insertion.

- Monthly measurement of the catheter-related bacteremia (CRB) rates.

The data from 103 ICUs was analyzed. The average CRB rate dropped from 2.7 episodes/1000 days CVC to 0/1,000 days CVC three months from the start, the average dropping from 7.7 episodes/1000 days CVC at the start to 1.4 at 16-18 months ($p<0.002$). The regression model showed a significant reduction in the infection rates, the incidence rate having dropped from 0.62 (95% CI: 0.47-0.81) to 0 three months following the start of the intervention and 0.34 (95% CI: 0.23-0.50) from 16 to 18 months. This intervention was more highly effectively in the smaller-sized, non-teaching hospitals.

In Spain, most of the Health Departments of the different Autonomous Communities have set out recommendations or guides for handling vascular catheters. Similarly, different national and international scientific societies have prepared their own recommendations. In our country, both the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC) and the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC) has set out their own guides through different working groups: the Infectious Diseases Working Group (GTEI-SEMICYUC) and the Hospital Infection Study Group (GEIH-SEIMC[5, 6]). Lastly, standards have been drafted at each hospital for inserting and maintaining vascular catheters following the general recommendations, on which the hospital Infections Committees have collaborated. However, the preparation of the guides or recommendations for reducing catheter-related infections has had very little influence on lowering the primary and/or catheter-related bacteremia rates. Therefore, it is necessary for more ambitious intervention programs to be implemented with the active participation of all of the groups involved in providing care for critical patients.

Through the Infectious Diseases Working group (GTEI), the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC), in conjunction with the Quality Agency of the Spanish Ministry of Health and Consumer Affairs, prepared a multifactorial project aimed at implementing the Michigan strategy in Spain's ICUs. This document presents the results of the pilot study conducted for evaluating the feasibility of this project.

1.1. Material and Method

The basic aspects of the intervention for the handling of vascular catheters in patients hospitalized in ICUs were structured along the following lines:

Healthcare Personnel Training and Information

All of the personnel of the units providing care for critical patients should take a two-hour on-line training course summarizing the essential aspects of catheter-related infections, particularly their clinical impact and the preventive measures. A record was to be made of the percentage of personnel at each ICU who had passed this course.

Intervention Content Dissemination

The recommended measures for follow-up (checklist, basic CVC insertion and maintenance recommendations, daily objectives, informative poster) were presented to all of the departments at joint sessions held for both physicians and nurses. Supporting graphic material serving as reminders of the intervention aspects were supplied. A physician and one nurse were designated for assuring full compliance with the intervention.

Pinpointing the Weak Points in Catheter Handling

The recommendation was made that discussions be held of recent cases of patients hospitalized on the unit who had developed a CRB as well as the results of the

checklists on inserting the CVCs. Every month, the weak points in catheter handling were to be pinpointed, discussed and objectives proposed for the improvement thereof over the following months.

Catheter-Related Bacteremia Study and Definitions

In view of any suspected catheter-related bacteremia, it was recommended that two pairs of blood cultures by percutaneous puncture be extracted and that the catheter be removed or replaced, the distal 5 cm then being cultured employing semi-quantitative methods. The procedures for catheter removal or replacement and the blood extraction for cultures were described in the procedures manual. When it were not to be possible to remove the catheter, it was to then be replaced at another point of insertion. Only in exceptional situations, when further catherterization entailed a high risk, could the replacement of the catheter by means of a guide, in the same insertion site, be considered, the catheter removed in this situation then always being subsequently cultured. In the event that the catheter in question were to test positive, it was recommended that the catheter be changed to another puncture site.

Catheter-related Bacteremia Definitions

- *Catheter-related bacteremia (or fungemia)(diagnosis following removal):* Isolation of the same microorganism (species and identical antibiogram) in blood culture extracted from peripheral vein and in a quantitative or semi-quantitative catheter tip culture in a patients with clinical signs and symptoms of sepsis without any other apparent focal point of infection. In the case of Coagulase-Negative Staphylococcus (CNS), the isolation of the microorganism in at least 2 peripheral blood culture vials.

- *Catheter-related bacteremia (or fungemia)(diagnosis without removal of the venous line):* Signs and symptoms of sepsis, without any other apparent focal point of infection, in which the same microorganism is isolated in simultaneous quantitative blood cultures in a ratio of 5:1 or higher in the samples extracted via catheter in comparison to those taken by vein puncture.

- *Probably catheter-related bacteremia (or fungemia) in absence of catheter culture*: Signs and symptoms of sepsis without any other apparent focal point of infection and a positive blood culture, in which the symptoms disappear at 48 hours following the removal of the venous line. This clinical condition is known as primary bacteremia.

- *Infusion fluid-related bacteremia (or fungemia)*: Signs and symptoms of sepsis without any other apparent focal point of infection, with isolation of the same microorganism in the infusion fluid as in the percutaneously extracted blood culture. This is classified as secondary bacteremia.

- *Catheter-related infection*. In absence of blood cultures or with negative blood cultures, the presence of a catheter tip culture with growth of > 15 ufc, accompanied by signs and symptoms of infection in absence of another known point of infection is considered to be a catheter-related infection. This is not considered to be bacteremia.

Patient Safety Teams

Teams or working groups were to be created at each hospital for assuring the safety of hospitalized patients. The physician and nurses responsible for implementing the interventions for preventing catheter-related bacteremias in critical patients were to serve on said working group.

Safety Climate Measurement

A validated, standardized questionnaire, the Spanish version of the Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety, was used.

Adhesion to the "Clean Hands" Campaign

The implementation of the campaign put forth by the WHO and the Spanish Ministry of Health and Consumer Affairs for improving hand hygiene was encouraged. It was recommended that checks of proper hand hygiene practices be made.

1.2. Participating Hospitals

This intervention was suggested to three Autonomous Communities, with 3 intervention units and 3 control units.

- Castile and Leon:
  - Intervention: Hospital General Yagüe (Burgos), Hospital Clínico (Salamanca), Complejo Hospitalario de Palencia (Palencia Hospital Complex).
  - Control: Hospital General de Segovia, Hospital Virgen de la Concha (Zamora), Polyvalent ICU of the Hospital de León
- Andalusia:
  - Intervention: Trauma ICU of the Hospital Virgen del Rocío (Seville), Hospital Puerta del Mar (Cadiz) and Surgical Medical Center of Granada.
  - Control: Hospital Carlos Haya (Malaga), Hospital Macarena (Seville), Hospital Torrecárdenas (Almeria).
- Catalunya:
  - Intervention: Hospital Vall d´Hebrón (General ICU and Pathology Unit) of Barcelona, Hospital del Mar (Barcelona), Hospital de Mataró.
  - Control: Hospital Josep Trueta (Girona), Hospital Bellvitge (Hospitalet de Llobregat), Hospital de Granollers

A preparatory meeting was held on September 13, 2007, with the attendance of two representatives (physican and nurse) from each ICU taking part in the pilot study (both the intervention and control participants). The materials to be used were provided, including a Powerpoint presentation for presenting the program to the Departments.

The pilot study was conducted throughout the October 1 - December 31, 2007 period.

1.3. Data Collection and Statistical Analysis

The bacteremia rates of each participating unit were to be reported monthly. For entering the data, the on-line ENVIN-HELICS ICU-acquired infection surveillance program http://hws.vhebron.net/envin-helics/, was employed, using the simplified version (risk factors calculated by critical unit, not measured as the patients' individual risk factors) by entering the number of patients with a CVC and the ICU-acquired bacteremias, both the primary and catheter-related bacteremias, as well as the secondary bacteremias of another focal point. The incidence density (ID) of primary bacteremia (PB) and CVC-related bacteremia (CB) per 1000 days of CVC and the IC of secondary bacteremias (SB) per 1000 days of hospitalization were calculated as a quality control which was to confirm that the reduction in PB+CB was not due to their being diagnosed as SB.

A comparison was drawn between the results fro the 3 months of intervention and the historical results of the immediately previous 3 years (2004, 2005 and 2006) of

the same units which were taking part in the pilot study. The Chi-square test was used for evaluating the differences between the periods compared. The statistical level accepted as significant was 5% ($p<0.05$).

1.4. Results

Participation

Of all the ICUs proposed for taking part in the pilot study, the required information was not furnished in two cases (one intervention unit and one control unit) in one same Autonomous Community. To the contrary, two ICUs took part at one hospital in the intervention group, a total of 17 ICUs (9 intervention units and 8 control units) therefore having been evaluated in the end.

Absolute Data

The number of hospital stays, catheter days, primary bacteremias, catheter-related bacteremias and secondary bacteremias of all the ICUs, those of intervention alone and the controls alone are shown in Tables I-II and III. The data refers to years 2004, 2005 and 2006 and to the 2007 study period. The number of ICUs varies over the years, given that not all of the units had been incorporated into the surveillance program during the previous years.

Rates

The PB+CB, CB and SB Dis are shown in Figures 1, 2 and 3. A significant difference is noted with regard to the PB and/or CB ID, there being no changes in the SBs, both in the overall ICUs, as well as in both the intervention and also the control ICUs. On analyzing the data by Autonomous Communities (Fig. 4): in Community A, the ID in the intervention ICU is found to have dropped significantly, but not so in the control ICU; in Community B, the significant drop being that of the control ICU; whilst in Community C, there is a drop in those of both the intervention and control ICUs.

Dissemination Outcomes and Personnel Involvement

- Informative sessions. Those responsible for each unit estimated that in most of the ICUs, sessions were held by professional levels and shifts. In one Unit, a presentation was given solely to physicians, not to nurses, the rates having risen in this ICU. In another two units, there was a delay in the presentation for different reasons.
- Involvement on the part of the professional. According to those in charge, involvement was generally greater among nurses. At some hospitals, well-hones working teams were formed. Although there has been little institutional support, no hindrances were encountered. Some hospitals have considered this project for possibly incorporating it into their management by objectives (MBO) process.
- Cases of reticence to change numbered fewer than expected. In some individual case, some lack of collaboration was detected as a show of job-related revindications.
- Nurses played the leading role. Although they generally accepted the role assigned, they were sometimes not willing to tell the physicians what they should do (i.e. the daily reminder).
- Posters: Small-sized posters were used. Over the course of time, they go unnoticed. It is suggested that several different posters be made and progressively changed so as to continue drawing attention.

Training Outcomes

- Training module. Compliance varied from 100% on some ICUs to others where the percentage was not recorded. There was a certain degree of reticence toward taking the examination, as it was not mandatory, out of a sense of modesty on its not being anonymous and not guaranteeing any credits.

Strategy Compliance Outcomes

Fig. 5 shows the percentage of compliance with the different aspects checked, being over 90% in all cases with the exception of the use of chlorhexidine, which was 17% on one of the units.

- Checklist: The total number of CVCs checked by way of the checklist during the insertion process was 415, 60 (40-112) CVC per ICU. The number recorded out of the total number of insertions was estimated at approximately 90%. The corrections: there were only 36 (8.6%), ranging on the different ICUs from 6 to 12. The catheters were elective in approximately 60% of the cases recorded. Problems were found to exist as regards interpreting the procedure classification (elective vs. emergency).
- Insertion material setups. The instittutions have been found to be somewhat slow to act as regards this point. These setups were not created at any hospital during the pilot study.
- Chlorhexidine. Some professionals initially expressed a dislike for the transparency of this disinfectant as well as entertaining certain doubts regarding its effectiveness. There was also some difficulty regarding obtaining this disinfectant through some Pharmacies.
- Removal of unnecessary catheters. No quantified in general. At one ICU, the number of days with a CVC and other devices (UCs) was found to have been shortened as compared to the previous periods as a result of the program.
- Daily decision list. Used to varying degrees. Taken as being overly repetitive over the course of time. Suggested to be included in a broader hardcopy list to be completed daily.
- Clean hands campaign. Not carried out at most hospitals. Posters were hung at one and another ICU. On one unit, hydro-alcohol solutions placed by the patients' bedsides were incorporated during the pilot study.

Safety Culture Outcomes

- Survey gauging the safety climate. A total of 438 employees answered the survey. More than half of the personnel surveyed considers there not to be sufficient personnel to deal with the care load, 51.6% stating working under too much pressure. A total of 43% considers having temporary personnel as being detrimental to patient safety.
- A total of 23% of those surveyed stated that there are patient safety-related problems on their unit. A total of 53.4% considers that they do have activities aimed at improving safety, 58.5% stating that when failures in safety are detected, corrective measures are taken, but only one third of those surveyed considers themselves to be informed concerning the problems which arise on their unit or in their department, less than 40% saying that on the unit where they work, the errors are discussed and corrective measures sought.
- Similarly, solely 40% of those surveyed considers there to be good cooperation among units/departments, the same percentage considering that their superiors value their suggestions for improving patient safety. A total 58.2% are of the opinion that the administration / management of their hospitals does not provide a safer working climate, over half (54.2%)

of those surveyed considering that the administration / management only takes an interest when there are problems.

- However, on scoring the degree of safety, the average score (SD) given 7.02 (1.69), although 22.4% of those surveyed did not answer this question.

1.5. Discussion

This pilot study shows that it was possible to reduce the catheter-related bacteremia rate in critical patients by means of a multifactorial intervention which included two supplementary activities: 1) specific, standardized measures related to CVC handling and insertion 2) measures aimed at promoting the safety culture in everyday work.

The CVC-related activities consisted of six basic measures accompanied by a maximum degree of evidence[7], Center for Disease Control and Prevention (CDC) Category IA recommendation. To the measures implemented by the Michigan study, the hygenic handling of the catheters was added, given the characteristics of the Spanish ICUs with patients who remain hospitalized in these units for longer periods of time and whose catheterizations are also longer than in U.S. patients. In fact, as is revealed by the ENVIN study data, the average length of time for the onset of CBR nears two weeks following admission to an ICU. This probably reflects that in the physiopathology of the development of bacteremia in our environment, the endoluminal route (associated to catheter care) may be of greater importance than the exoluminal route (associated to the point in time of insertion), it thus being important to reinforce hygienic handling, as was done in our study.

The checklist on inserting the catheter showed an excellent following of the recommendations, with over 90% compliance, the use of chlorhexidine having failed on solely one unit due to difficulties in obtaining the same. Nor were any difficulties encountered on giving nurses power during the insertion control process, something which had been cause for concern before the fact. As regards the recommendation of avoiding femoral sites, this site was used overall solely in 18% of the insertions, whilst the site was jugular in 26%, being another site entailing risk of infection. The variability among units on selecting the point of insertion was very high, but it is important that solely 1/3 of the CVCs were in high-risk locations.

The measures aimed a promotion safety focused, in addition to gauging the safety climate, on searching out errors related exclusively to catheter use, without including any other possible safety-related errors. This was one aspect which was not carried out to any great degree, given that there was no specific training, although there were some specific recommendations, such as educating the personnel in the evidence, optimizing the handling with everyday objectives or pinpointing errors by suggesting objectives for improvement. The training which has shown itself to be highly effective in preventing nosocomial infection[8], was one of the key aspects of this project, although the percentage of personnel who completed the training module and passed the examination was not counted. The daily objectives referred solely to catheter handling, whilst, in the U.S. study, they covered all aspects of the patient. As regards pinpointing errors, the handling was irregular, given that on some of the units, specific groups were trained who worked identifying errors and objectives for improvement, but on other ICUs, this aspect was not carried out. Nor was the recommendation generally followed of holding informative sessions, reporting the rates and discussing the cases of patients with bacteremia. The survey for gauging the safety climate showed a good opinion, given that the average score was 7, a grade of “B”, although up to one fourth of the personnel did not answer this question.

The rates were lowered to a lesser degree than what was achieved in Michigan, but the study period was only three months long and thus entailed limitations on the

progression, apart from there having been certain problems in the implementation thereof at one ICU and another and as to the safety aspect not being as all-encompassing as in Michigan. On the other hand, those responsible for reach unit – a physician and a nurse – did not avail of the resource of extra time for implementing the program, unlike the case of Michigan. Another difference was that the involvement on the part of the administrators was non-existent.

The important aspect of this study was the secondary bacteremia rate having remained the same, which assures that the drop in the CRB was not at the expense of "placing" the bacteremias diagnosed under a different description, but rather that this was an actual drop. Hence, the surveillance of all episodes of bacteremia makes it of a higher quality than that of the U.S. study, which did not validate this aspect.

Another aspect to which some thought must be given is that the drop in the rates was found not only in the intervention ICUs, but also in the control ICUs. There may be many explanations for this. On one hand, the "surveillance" effect, a common phenomenon which shows an improvement in any indicator when a study is conducted thereof with the knowledge of the healthcare professionals involved. The fact that the control ICUs were familiar with the intervention methodology not only due to the publication of the Michigan study, but also as a result of having attended the preparatory meeting and availing of the tools to use might also have a bearing. At said meeting, all of the participants expressed their desire to implement the strategy and not to be mere onlookers. It is difficult not to be influenced by the evidence that the adverse effects such as infections can be controlled, especially with such simple measures as those implemented in this project. The improvement was greater on those units which had the highest starting rates, which generally was the case for the gratest part on the control ICUs, but it must be said that the only Autonomous Community which did not lower its rates in the control ICU was Autonomous Community A, from which no representative attended; and that Autonomous Community B, from which all its representatives were in attendance, was that which showed the gratest reduction in the control ICUs. The "contamination" due to a knowledge of the methodology may apparently have had a bearing on these results.

The fact that this pilot study was conducted solely in three Autonomous Communities and that the ICUs must have had experience in nosocomial infection surveillance limited the number of ICUs which could take part and hindered the comparability of the control and intervention groups, which differed from the baseline.

In conclusion, this is an experience which confirms the effectiveness of a multifactorial program on reducing CRBs which has identified aspects regarding which there is room for improvement in the protocol which must be implemented nationwide, in which the implementation of the improvement of the safety culture will be that requiring the gratest effort.

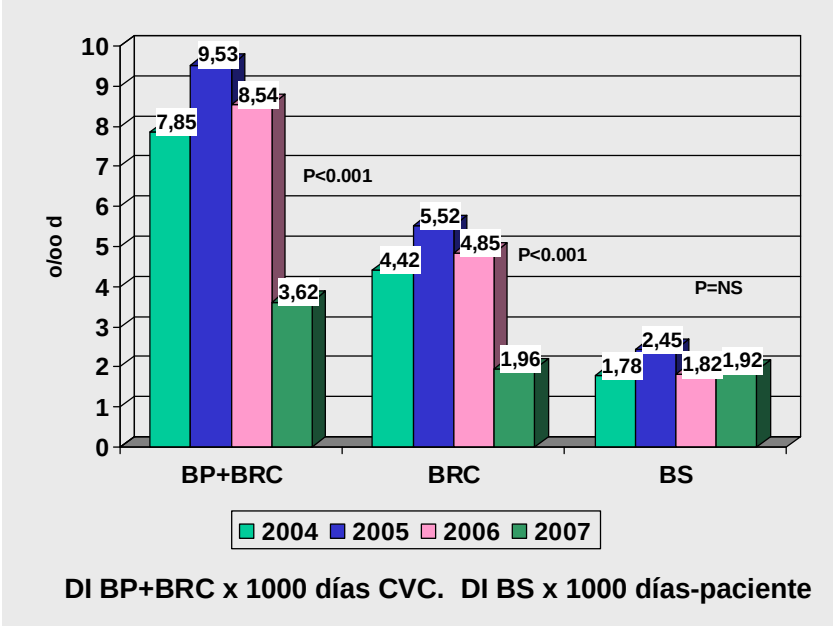
2 Annex 1

Table 1. Results of all of the participating ICUs

Year	Days/patient	Days-CVC	CRB	PB+CRB	SB
2004 (10 ICUs)	15,678	9,034	40	71	28
2005 (13 ICUs)	15,091	11,220	62	107	37
2006 (16 ICUs)	19,732	13,808	67	118	36
2007 (17 ICUs)	22,298	19,885	39	72	43

CRB: Catheter-Related Bacteremia. PB: Primary Bacteremia SB: Secondary Bacteremia.

Fig. 1: All ICU (intervention and control) bacteremia rates



BP + BRC = PB + CRB BRC = CRB BS = SB

DI BP+BRC x 1000 dás CVC = PB+CRB ID x 1000 days CVC

DI BS x 1000 días-paciente = SB ID x 1000 patient days

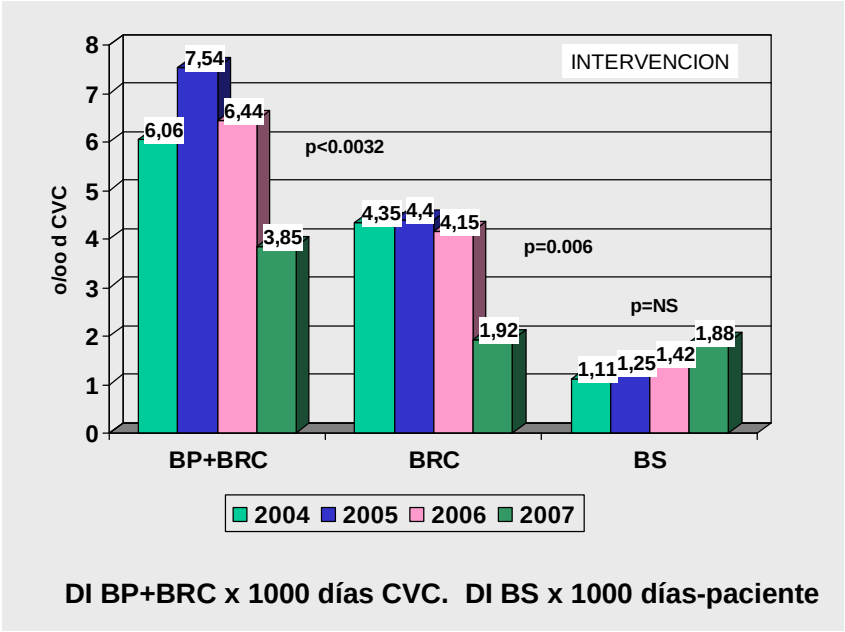
PB + CRB ID: Primary bacteremia and catheter-related bacteremia incidence density. CVC: Central Venous Catheter. SB ID: Secondary bacteremia incidence density.

Table 2. Intervention ICU Results

Year (No. ICUs)	Days-patient	Days-CVC	CRB	PB + CRB	SB
2004 (5 ICUs)	12,651	6,434	28	39	14
2005 (7 ICUs)	10,420	7,960	35	60	13
2006 (8 ICUs)	12,651	9,164	38	59	18
2007 (9 ICUs)	13,319	11,432	22	44	25

CRB = Catheter-Related Bacteremia PB: Primary Bacteremia SB: Secondary Bacteremia

Fig. 2: Intervention ICU bacteremia rates



DI BP+BRC x 1000 días CVC. DI BS x 1000 días-paciente

INTERVENCIÓN = INTERVENTION

BP+BRC = PB+CRB BRC =CRB BS = SB

DI BP+BRC x 1000 dás CVC = PB+CRB ID x 1000 days CVC

DI BS x 1000 días-paciente = SB ID x 1000 patient days

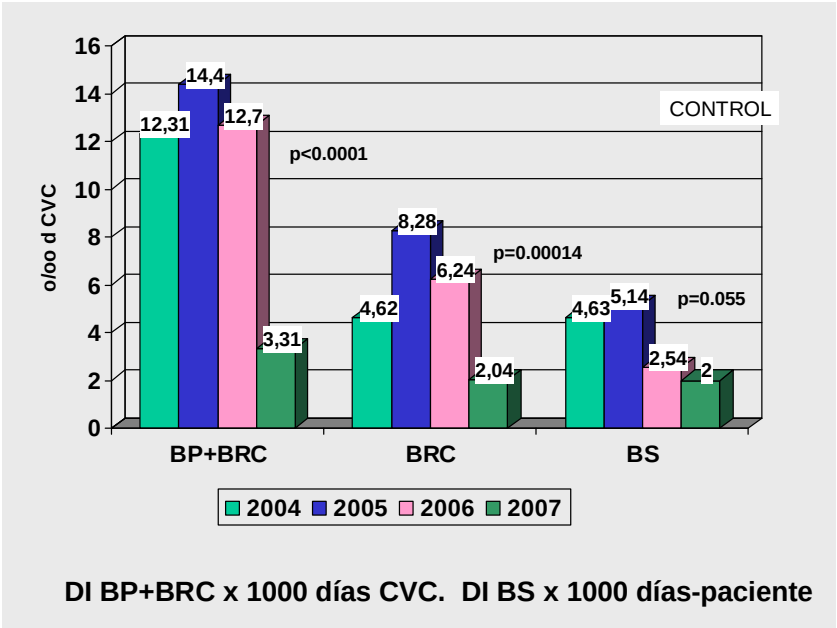
PB + CRB ID: Primary bacteremia and catheter-related bacteremia incidence density. CVC: Central Venous Catheter. SB ID: Secondary bacteremia incidence density.

Table 3. Control ICU Results

Year	Days-patient	Days-CVC	CRB	PB-CRB	SB
2004 (5 ICUs)	3,027	2,600	12	32	14
2005 (6 ICUs)	4,671	3,260	27	47	24
2006 (8 ICUs)	7,081	4,644	29	59	18
2007 (8 ICUs)	8,979	8,453	17	28	18

CRB: Catheter-Related Bacteremia PB: Primary Bacteremia SB: Secondary Bacteremia

Fig. 3: Control ICU bacteremia rates



DI BP+BRC x 1000 días CVC. DI BS x 1000 días-paciente

CONTROL = CONTROL

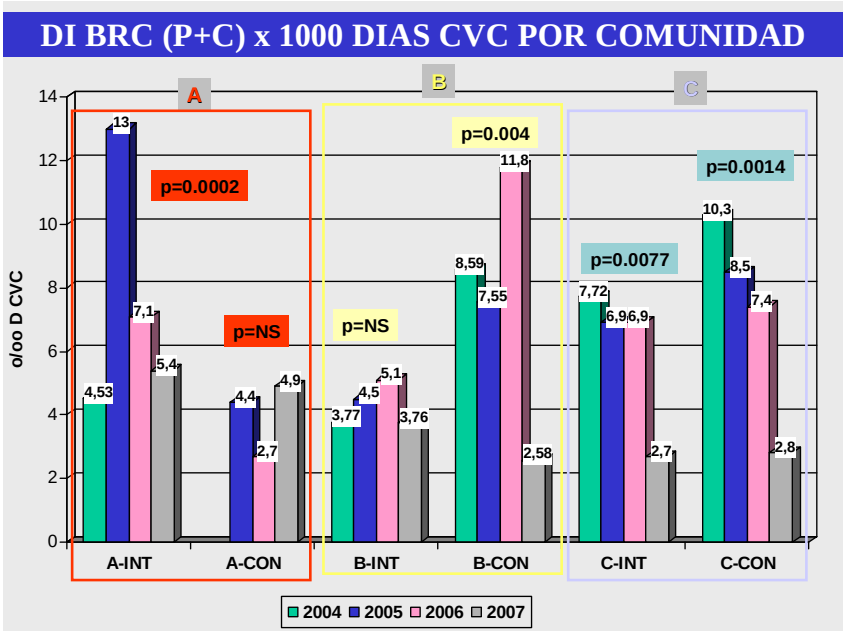
BP+BRC = PB+CRB BRC =CRB BS = SB

DI BP+BRC x 1000 dás CVC = PB+CRB ID x 1000 days CVC

DI BS x 1000 días-paciente = SB ID x 1000 patient days

PB + CRB ID: Primary bacteremia and catheter-related bacteremia incidence density. CVC: Central Venous Catheter. SB ID: Secondary bacteremia incidence density.

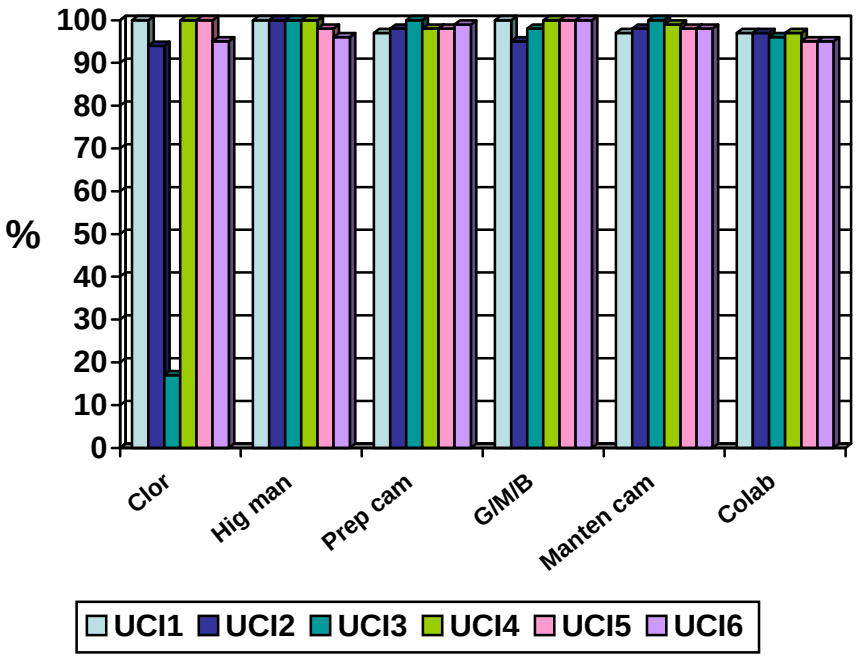
Fig. 4. Catheter-related bacteremia + primary bacteremia, catheter-related bacteremia incidence density on the intervention and control ICUs in the three Autonomous Communities



DI BRC (P+C) x 1000 DIAS CVC POR COMUNIDAD = CRB (P+C) ID x 1000 DAYS CVC BY AUTONOMOUS COMMUNITIES

A-INT: Autonomous Community A intervention units. A-CON: Autonomous Community A control units. B-INT: Autonomous Community B intervention units. B-CON: Autonomous Community B control units. C-INT: Autonomous Community C intervention units. C-CON: Autonomous Community C control units.

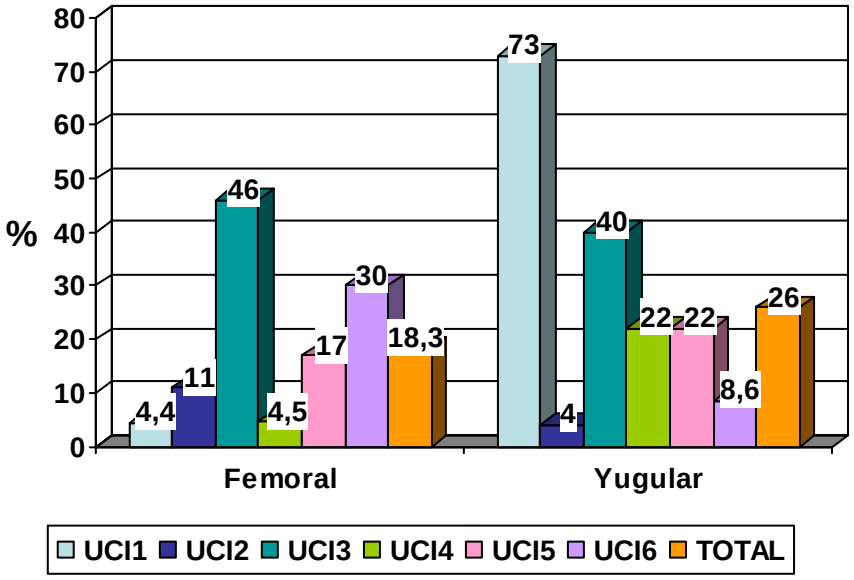
Fig. 5. Percentage of compliance with the different aspects checked at CVC insertion



Chlor: Chlorhexidine. Hand hyg: Hand hygiene; Prep area: Preparation of the area; G/M/C: Use of gloves, mask, coat; Keep sterile: keeping area sterile during the procedure; Collab.: the collaborators have maintained sterile conditions.

Fig. 6. CVC insertion in femoral and jugular sites on 6 participating ICUs

Femoral = Femoral Yugular = Jugular



3 Bibliography

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