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SafeBreak Vascular Vet
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# Evaluation of the Use of a Force-Activated Separation Device (SafeBreak® Vascular) in a Prospective, Randomized Controlled Trial in Dogs

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## Background

Intravenous catheters (IVCs) play a vital role in the treatment of hospitalized animals by allowing for administration of intravenous (IV) fluids and medications. However, IVC complications, including infiltration, dislodgement, phlebitis, and occlusion, may occur.[1,2] These complications may lead to consequences for the patient including infection, pain, failure to deliver prescribed treatments, and with repeated catheterization, venous depletion becomes a risk. These complications and consequences lead to increased costs to the hospital and client.

The IVC complication rate has been well-documented in human medicine with reported rates between 35% and 50%.[2] The rate of IVC complications in hospitalized cats has been reported as 21.4%, with complications including phlebitis, infiltration, occlusion, removal by patient, and the formation of edema.[1] The rate of IVC complications in dogs has not been reported. The objective of this study was to determine the rate of IVC complications in hospitalized dogs and to determine if the use of SafeBreak Vascular reduced the rate of IVC complications in hospitalized dogs.

SafeBreak Vascular is a new medical device designed to separate when excessive tension is exerted across an IVC. When SafeBreak separates, the harmful force placed on the IV line is prevented from reaching the IVC site, keeping the patient's IVC intact. It is the first in a new class of infusion management devices known as Force-Activated Separation Devices.

Figure 1 shows the SafeBreak Vascular device. The device is placed between the long IV administration tubing and the needleless connector/extension tubing set that is attached to the patient's IVC. The device separates when a force greater than 4lbs is placed on the IV line, but leaves the patient's IVC intact. Upon separation, valves on each side of the device close to prevent the loss of fluids/medications from the IV pump and blood loss from the patient side.

*Figure 1. SafeBreak Vascular*

If attached to an infusion pump, the distal occlusion alarm sounds when the valve on the IV tubing closes, letting the technician know that the IV line needs attention. The separated SafeBreak Vascular can be thrown away. A new, sterile SafeBreak Vascular can be installed, and the patient's IV infusion can be resumed.

## Methods

A prospective, randomized controlled clinical trial was performed at a small animal veterinary teaching hospital. Hospitalized dogs receiving IV fluids were randomized to the SafeBreak group or to the control group. Dogs in the SafeBreak group had the device installed in their IV line according to manufacturer instructions, and the date/time of each separation was documented. Figure 2 shows a representative patient with SafeBreak installed.

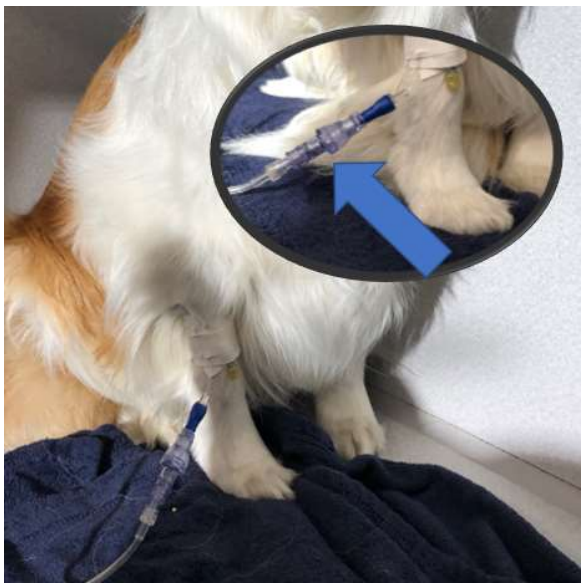

*Figure 2 – Representative Canine Patient with SafeBreak Installed in the IVC*

For dogs in both groups, all IVC complications requiring IVC restart or line replacement were documented, and each complication was classified as infiltration, phlebitis, dislodgement, occlusion, or line breakage.

Data collected included: patient medical record number, age, breed, sex, neuter status, weight (kgs), reason for hospitalization, number/type of catheter complications, patient demeanor, catheter dwell time, length of hospitalization, and number of SafeBreak disconnects. All separated SafeBreaks were replaced as long as an IVC remained in place. If the patient suffered an IVC complication, the catheter was replaced if the patient required continued treatment.

Patient characteristics were compared between groups using independent samples t-test for normally distributed continuous variables. Length of hospitalization was not normally distributed and therefore a Mann Whitney U test was used. A chi-square test of proportions or Fisher's exact test (when cell counts were <5) was used to compare categorical variables between groups for patient characteristics and rate of IVC complications. A multivariate logistic regression was also performed for the primary outcome, total IVC complications, to examine if treatment group predicted having an IVC complication while adjusting for relevant covariates including weight, breed size, surgery, and length of hospitalization.

## Results

Of the 367 patients enrolled in the per protocol population, 187 patients were randomized to the control group and 180 patients were randomized to the SafeBreak group. Patient characteristics are displayed in Table 1.

| Table 1: Patient Characteristics | | | |
|---|---|---|---|
| **Characteristics** | **Sub Category** | **Control (n=187)** | **SafeBreak (n=180)** |
| **Age (yr)** | Mean ± SD | 6.68 ± 5.32 | 6.74 ± 4.68 |
| **Weight (kg)** | Mean ± SD | 22.21 ± 14.71 | 23.02 ± 13.60 |
| **Breed Size** | Small (< 5kg) | 19 (10.2 %) | 17 (9.4%) |
| | Medium (5 – 19.99kg) | 66 (35.3%) | 56 (31.1%) |
| | Large (20 – 39.99 kg) | 79 (42.2%) | 90 (50.1%) |
| | Giant (> 40kg) | 23 (12.3%) | 17 (9.4%) |
| **Hospitalization Unit** | Critical Care | 117 (62.6%) | 113 (62,8%) |
| | Intermediate Care | 67 (37.2%) | 70 (37.4%) |
| **Infusion Time (days)** | median, IQ | 3.0, 2.0 | 3.0, 2.0 |

Overall, the patients were 6.71±5.00 years old, almost half (46%) were large breed dogs, and the majority were cared for in the critical care unit (62.7%). There were no significant differences in patient characteristics between groups (all Ps >.05), with the exception of length of hospitalization, which may be considered an indicator of infusion time (P<.05).

The control group had 46 IVC complications in 187 patients (24.6%), whereas the SafeBreak group had 16 IVC complications in 180 patients (8.8%). The SafeBreak group experienced a total of 327 SafeBreak separations that occurred in 52% of the patients (97 out of 180). The 52% of patients that experienced a SafeBreak separation event had an average of 3.4 separations per patient. 48% of patients (83 out of 180) experienced no SafeBreak separations. To test the primary outcome, proportions of the total and individual IVC complications were compared between groups using a chi-square analysis or Fisher's exact test. SafeBreak patients experienced 65% fewer IVC complications than control patients (p<0.001), which was statistically significant. When the specific types of IVC complications were compared individually, the SafeBreak group had statistically significant fewer instances of line breakage (p=.002), dislodgement (p=.038), and phlebitis (p=.036). The occurrence of infiltration and occlusion showed no statistical difference between the two groups. Information regarding individual complications as well as a comparison of IVC complications between groups can be found in Table 2.

| Table 2: Summary of IVC Related Complications | | | | |
|---|---|---|---|---|
| **IVC Complication** | **Complications in Control Group (n=187)** | **Complications in SafeBreak Group (n=180)** | **Reductions in # of Complications from Control to SafeBreak Group** | **P Value** |
| **Line Breakage** | 13 | 1 | 92% | **.002** |
| **Dislodgement** | 10 | 2 | 80% | **.038** |
| **Phlebitis** | 15 | 5 | 67% | **.036** |
| **Infiltration** | 5 | 8 | (-38%) | .314 |
| **Occlusion** | 3 | 0 | 100% | .250 |
| **Totals** | **46** | **16** | **65%** | **<.001** |

Overall IVC complications were reduced by 65% in the SafeBreak group when compared to the control group. Line breakage was reduced by 92%, dislodgement was reduced by 80%, phlebitis was reduced by 67%, and occlusion was reduced by 100%. The SafeBreak group had 38% more instances of infiltration than the control group, which was not statistically significant.

In addition to a statistically significant decrease in IVC complications between the two groups, there were also significantly fewer patients in the SafeBreak group that experienced IVC complications when compared to the control group (p=.004).

When adjusting for relevant covariates including weight, breed size, surgery, and length of hospitalization, there remained a significant difference in the total frequency of IVC complications between the two groups (P=.001, 95% CI = 0.16, 0.61). There also remained a significant difference in the number of patients with an IVC complication between the two groups after adjusting for these covariates (P= .005, 95% CI = 1.35, 5.17).

In the bivariate analysis, the length of hospitalization, which may be considered an indicator of infusion time, was significantly greater in the control group. However, when length of hospitalization was adjusted for the covariate analysis, being in the control group remained a significant predictor of having an IVC complication. That is, patients in the control group were still more likely to have an IVC complication compared to patients in the SafeBreak group, while accounting for the difference in length of hospitalization.

## Discussion

The primary endpoint of the study was to compare the rate of IVC complications between the SafeBreak and control groups. The study demonstrated that there was a statistically significant reduction in IVC complications, with an overall 65% decrease in complications in the SafeBreak group.

While the full benefit of SafeBreak is realized when used on 100% of patients for the duration of hospitalization, there may be a need for a clinic to discontinue the use of SafeBreak on those patients with excessive separations. In order to understand the impact of SafeBreak when discontinued prior to a patient's discharge from the hospital, a representative subset of patients experiencing three or less SafeBreak separations was selected.

In this study, there were 327 SafeBreak separations in 97 of 180 patients in the SafeBreak group. Of the 97 patients with SafeBreak separations, 39 patients experienced more than three SafeBreak separations. This was most commonly seen in dogs that were anxious/agitated or in young, active dogs.

An additional set of analyses was performed with a new sample set after the data for patients experiencing more than three SafeBreak separations were removed. This data is presented in Table 3. Only IVC complications occurring *after* the third SafeBreak separation were removed from the data set; those occurring prior to the third SafeBreak separation were included.

| Table 3: Summary of IVC Related Complications with Patients Experiencing >3 SafeBreak Separations Removed | | | | |
|---|---|---|---|---|
| **IVC Complication** | **Complications in Control Group (n=187)** | **Complications in SafeBreak Group (n=143)** | **Reductions in # of Complications from Control to SafeBreak Group** | **P Value** |
| **Line Breakage** | 13 | 1 | 92% | **.006** |
| **Dislodgement** | 10 | 2 | 80% | .081 |
| **Phlebitis** | 15 | 2 | 86% | **.010** |
| **Infiltration** | 5 | 3 | 40% | 1.00 |
| **Occlusion** | 3 | 0 | 100% | .267 |
| **Totals** | **46** | **8** | **83%** | **<.001** |

In patients who experienced more than three SafeBreak separations, overall IVC complications were reduced by 83% in the SafeBreak group when compared to the control group. Line breakage was reduced by 92%, dislodgement was reduced by 80%, phlebitis was reduced by 86%, infiltration was reduced by 40%, and occlusion was reduced by 100%. Of note, the occurrence of line breakage, dislodgement, and occlusion was unaffected by excluding patients with more than three SafeBreak separations.

Excluding dogs with more than three SafeBreak separations, there were 58 patients (41%) that experienced 93 separations. The 41% of patients that experienced a SafeBreak separation event had an average of 1.6 separations per patient. 58% of patients (85 out of 143) experienced no SafeBreak separations. 2.1% of patients (3 out of 143) experienced an IVC complication as well as a SafeBreak separation.

When adjusting for potential covariates, there remained a significant difference in the total frequency of IVC complications between the two groups (P= <.001, 95% CI = 2.39, 14.15) and in the number of patients with a IVC complication between the two groups after adjusting for covariates (P = .001, 95% CI = 1.96, 11.49).

The financial impact to the client when placing an IVC will vary slightly between hospitals. Costs associated with IVC placement will include supplies (cleaning supplies, IVC, t-port, gloves, tape, etc), the technician time, and hospital overhead. Placing an IVC generally requires two technicians, one to restrain the animal and one to place the catheter. As a representation, the cost to the client for placing an IVC is approximately $70[3]. Based on investigational site experience, it takes approximately 20 minutes to place the IVC and only one set of supplies are used. Additional costs may include the use of additional supplies (i.e. more than one IVC) and the cost of sedation when needed. In addition, IVC placement may require more than one attempt and may require significantly more time and the use of sedation. This would increase the cost of placement dramatically.

When considering patients that could have multiple IVC complications requiring catheter replacement, the cost to the client could prove to be significant. For example,

in a patient with three IVC complications, there would be a cost of $280 to the client ($70 for placement of the initial catheter and $210 for placement of the three additional catheters). Assuming that the three IVC complications would be prevented with the

use of SafeBreak, the cost to the client is reduced dramatically. With a representative SafeBreak cost of $7, the cost to the client would be reduced to the cost of the initial catheter placement ($70) and the cost of three SafeBreak devices ($21). The total client cost would be $91 versus $280 for replacement of three IVCs, for a total client savings of $189. With an appropriate standard mark-up on each SafeBreak, the clinic can lower the overall cost of care for the client while increasing the profit generated for that episode of care.

In addition to the financial burden of catheter replacement caused by IVC complications, there are also other "pains" associated with IVC complications. Patient sedation, venous depletion, patient agitation, multiple needle sticks, infection potential, and unnecessary technician time of already understaffed clinics are all factors that may be greatly reduced with the introduction of SafeBreak. SafeBreak replacement after separation can be performed by one technician in five minutes: no sedation, no additional needlesticks, and minimal disruption to the intravenous fluids or medication.

## Conclusion

This study demonstrated that using a Force-Activated Separation Device prevents harmful forces from causing IVC complications in canine patients. When used across all patients for their entire length of stay, the use of SafeBreak resulted in a 65% decrease in IVC complications compared to the control group. In situations where the cost of disposable devices is a concern, SafeBreak could be discontinued after the third separation event and still offer an 83% decrease in the rate of IVC complications.

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2. Helm RE, Klausner J, Klemperer JD, et al. Accepted but unacceptable: peripheral IV catheter failure. *J Infus Nurs* 2015;38(3):189-203.
3. Data on File

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