

# Surgical Considerations For Kcentra In Acute Surgical Procedures



## Indications

Kcentra®, Prothrombin Complex Concentrate (Human), is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA—eg, warfarin) therapy in adult patients with acute major bleeding or the need for urgent surgery or other invasive procedure. Kcentra is for intravenous use only.



## CONTACT

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## Problem

- Cardiovascular disease and embolic events are on the rise in the United States.
- Warfarin is used to treat individuals who are at increased risk of thrombotic events. These patients are often older with other comorbidities, which places them at increased risk of perioperative bleeding. Kcentra can rapidly decrease INR levels minimizing large amounts of blood loss during urgent procedures

## Methods

- This topic was addressed with student nurse anesthetists at AdventHealth University
- An extensive literature review was conducted on current, peer reviewed, evidence based research
- The data was compiled into an educational presentation, approved by the IRB
- Presentation was conveyed to 22 students
- Anonymous Pre-test given before educational presentation
- Post-test after education presentation
- Informed consent was obtained
- Statistical analysis was performed by a statistician and acquired results via a paired t-test

## Efficacy

In 2 head-to-head trials, Kcentra demonstrated superiority to plasma in 3 of 4 efficacy endpoints

Efficacy endpoint	Urgent Surgery/Invasive Procedures trial	Acute Major Bleeding trial
Effective hemostasis	Kcentra <i>superior</i>	Kcentra and plasma <i>equally effective</i>
Early INR reduction	Kcentra <i>superior</i>	Kcentra <i>superior</i>

## Literature Review

- Kcentra for urgent reversal of warfarin
  - Pts who receive chronic anticoagulation therapy are at significant risk for complications when faced with acute surgery (Rafaai et al., 2015).
  - Dosing is 25IU/Kg in an average volume of 90-100ml
- Chronic conditions in which Coumadin is used for:
  - A Fib
  - Heart Valve Replacement
  - DVT
  - Non Hemorrhagic stroke
- Kcentra is a prothrombin complex concentrate this is a relatively a new anticoagulant reversal agent.
- Kcentra contains all vitamin K dependent factors (II, VII, IX, X) as well as protein C and S (Milling et. al, 2016).
  - Requires less volume than the standard practice of giving FFP.
  - Effect of Kcentra last up to 24 hours
- Anesthesia implications with Kcentra
  - Kcentra's overall safety profile was comparable to FFP
  - Significant decrease in the number of fluid overload events compared to FFP (Milling et. all, 2016).
  - ICU length of stay decreased 5.8 days when Kcentra was used (Song et. al, 2014).
  - Can be used effectively for any blood type and can be produced in large quantities as needed.
  - Trali is increased by 40% with female multiparous donors.
  - Risk of Kidney injury

## Serious events occurring in both RCTs

Serious adverse reactions	No. (%) of subjects	
	Kcentra (N=191)	Plasma (N=197)
TE events*	13 (6.8%)	14 (7.1%)
Fluid overload events†	9 (4.7%)	25 (12.7%)
Deaths	13 (6.8%)	13 (6.6%)

## Results

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	VAR00001	40.91%	22	19.73855	4.20
	VAR00002	90.45%	22	10.45502	2.22

Paired Samples Test							
	Paired Differences Mean	t	df	Sig. (2-tailed)	95% Confidence Interval of the Difference		
					Lower	Upper	
Pair 1	VAR00001 -	-49.54545	25.35036	5.40471	-38.30574	-9.167	21

## Analysis and Conclusion

- Limitations: there was a small sample size (22), test was administered after a long strenuous clinical day
- The results did show a meaningful increase in average scores, from 40.9% to 90.5% with a P=0.001

## Findings

- The researchers concluded that there was a significant knowledge increase after the presentation of the educational PowerPoint
- This will help guide new anesthetists in the management of this growing population

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## References Available Upon Request