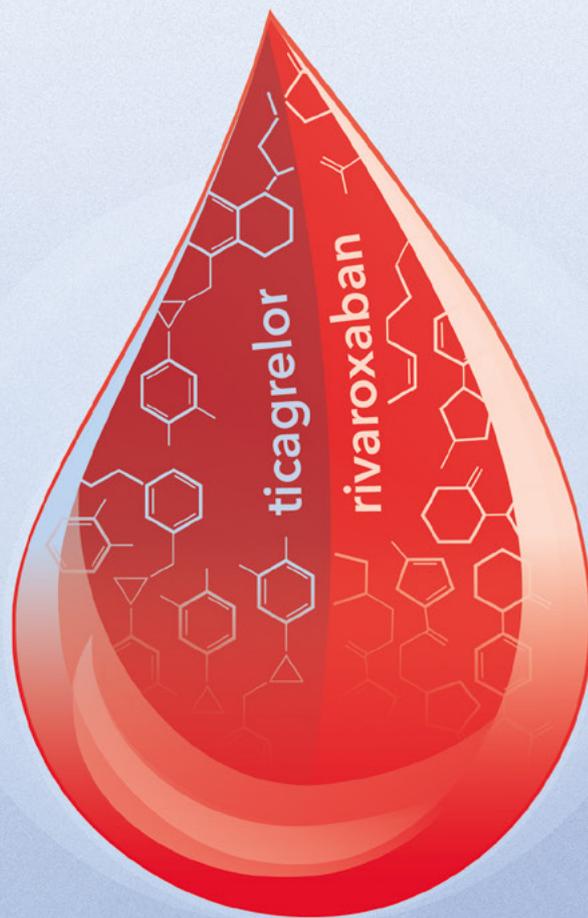


Reduce peri-operative bleeding risk in patients on ticagrelor / rivaroxaban

CytoSorb Therapy in urgent and emergent
cardiac surgery



NEW

Approved for intraoperative
ticagrelor / rivaroxaban removal
during cardiopulmonary bypass (CPB)⁽¹⁾

Background

Ticagrelor is a reversible inhibitor of the P2Y₁₂ platelet receptor and is indicated for the prevention of atherothrombotic events in patients with acute coronary syndromes (ACS) or a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event.⁽²⁾

Rivaroxaban, a factor Xa inhibitor, is a novel oral anticoagulant (NOAC) indicated for the prevention of stroke in patients with atrial fibrillation and for prevention or treatment of deep vein thrombosis and pulmonary embolism.⁽³⁾

In order to prevent bleeding complications both drugs should be discontinued prior to surgery:

- ≥ 3 days for ticagrelor^(4,5)
- ≥ 2 days for rivaroxaban^(3,4)

However, in case of urgent or emergent surgery with no time to wait, ticagrelor or rivaroxaban can lead to an increase in peri-operative bleeding.^(5,6)

CytoSorb reduces bleeding complications in emergent surgery patients by effectively removing **ticagrelor and rivaroxaban** from the circulation.^(7,8,9)

The CytoSorb CE label now also includes intraoperative **ticagrelor and rivaroxaban** removal during cardiopulmonary bypass.^(1,*)

Clinical outcome data⁽⁷⁾

43 patients emergency surgery with ticagrelor		55 patients		12 patients emergency surgery with rivaroxaban	
32 patients with intra-operative CytoSorb	11 patients control without CytoSorb			7 patients with intra-operative CytoSorb	5 patients control without CytoSorb
CPB + CytoSorb (n=32)	CPB alone (n=11)			CPB + CytoSorb (n=7)	CPB alone (n=5)
288 ± 63	353 ± 84	Procedure duration** (min; mean ± SD)	p<0.01***	184 ± 97	309 ± 50
21.9% (n=7)	45.5% (n=5)	Red blood cell (RBC) transfusion	p<0.02***	14.3% (n=1)	100% (n=5)
34.4% (n=11)	100% (n=11)	Platelet (PLT) transfusion	p<0.05***	28.6% (n=2)	100% (n=5)
350 [300 - 450]	890 [630 - 1025]	Chest tube drainage/24hrs (ml; median [IQR])	p<0.01***	390 [310 - 430]	600 [590 - 1000]
0% (n=0)	36.4% (n=4)	Re-thoracotomy	p<0.01***	0% (n=0)	40% (n=2)
2 [1 - 3]	3 [2 - 4]	Days in intensive care (median [IQR])	p<0.02***	2 [2 - 3]	6 [5 - 6]
11 [9 - 12]	14 [10 - 16]	Total length of stay (days; median [IQR])	p<0.03***	11 [10 - 13]	18 [18 - 20]

* The CE label of CytoSorb does not cover removal of any other anti-thrombotic medications.

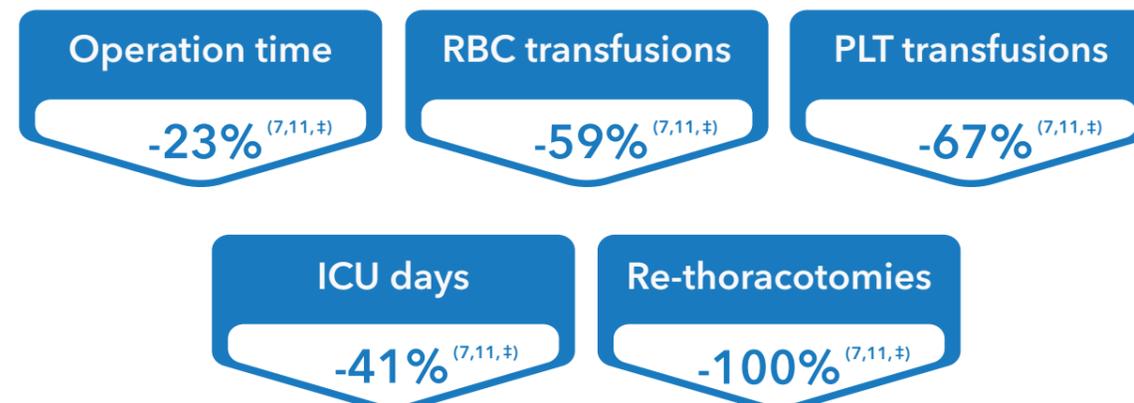
** Similar CPB/cross clamp time in both groups.

*** P-values reflect significant differences in the means between patients treated with CytoSorb and the control group, irrespective of the drug.

Health economic impact

> **CytoSorb has a high probability of saving costs.**^(10,11)

> Cost savings derive from fewer blood product transfusions and re-thoracotomies, and shorter stay in the intensive care unit / hospital.⁽¹⁰⁾



Conclusions according to the authors

"The intraoperative use of the CytoSorb hemoadsorption in patients with ticagrelor or rivaroxaban treatment undergoing emergency open-heart operations is a safe and effective method to reduce bleeding complications and to improve the postoperative outcome."⁽⁷⁾

"We recommend the use of **CytoSorb adsorption** for safety in patients undergoing emergency cardiac surgery and medication with ticagrelor or rivaroxaban."⁽⁷⁾

Study description⁽⁷⁾

CytoSorb adsorption during emergency cardiac operations in patients at high risk of bleeding

Hassan K, Kannmacher J, Wohlmuth P, Budde U, Schmoeckel M, Geidel S
Annals of Thoracic Surgery 2019;108:45-51

This study included 55 consecutive patients undergoing emergency open-heart operations who were at high risk of bleeding due to prior treatment with anti-thrombotic medications (43 patients on ticagrelor, 12 on rivaroxaban). In 39 of 55 cases, CytoSorb adsorption was installed into the cardiopulmonary bypass. Bleeding complications during and after surgery were analyzed in detail and compared to the 16 patients without CytoSorb (11 patients on ticagrelor, 5 on rivaroxaban).

‡ Weighted average calculated based on data provided by Hassan et al.⁽⁷⁾



CytoSorb integration into CPB

Example setup

▼ Watch Prof. Pascal Leprince and PD Dr. Stephan Geidel present the clinical outcome data

References (Clinical and *preclinical data):

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7. Hassan K et al., Annals of Thoracic Surgery 2019;108(1):45-51
8. * Angheloiu GO et al., J Am Coll Cardiol Basic Trans Science 2017;2:135-45
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11. Data on file

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The clinical and preclinical data and results obtained with the CytoSorb adsorber are not transferable to other products. CytoSorb should only be administered by personnel who have been properly trained in administration of extracorporeal therapies.

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