



Consensus on resuscitative endovascular balloon occlusion of the Aorta: A first consensus paper using a Delphi method



B.L.S. Borger van der Burg^{a,*}, B. Kessel^b, J.J. DuBose^c, T.M. Hörer^d, R. Hoencamp^{a,e,f}

^a Department of Surgery, Alrijne Hospital, Leiderdorp, the Netherlands

^b Department of Trauma, Hillel Yaffe Medical Center, Hadera, Israel

^c R Adam Cowley Shock Trauma Center, University of Maryland Medical System, Baltimore, USA

^d Department of Cardiothoracic and Vascular Surgery, Faculty of Life Science Örebro University Hospital, Örebro, Sweden

^e Defense Healthcare Organization, Ministry of Defense, Utrecht, the Netherlands

^f Leiden University Medical Centre, Leiden, the Netherlands

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ABSTRACT

Background: To further strengthen the evidence base on the use of Resuscitative Endovascular Balloon occlusion of the Aorta (REBOA) we performed a Delphi consensus. The aim of this paper is to establish consensus on the indications and contraindications for the use of REBOA in trauma and non-trauma patients based on the existing evidence and expertise.

Study Design: A literature review facilitated the design of a three-round Delphi questionnaire. Delphi panelists were identified by the investigators. Consensus was reached when at least 70% of the panelists responded to the survey and more than 70% of respondents reached agreement or disagreement.

Results: Panel members reached consensus on potential indications, contra-indications and settings for use of REBOA (excluding the pre hospital environment), physiological parameters for patient selection and indications for early femoral access. Panel members failed to reach consensus on the use of REBOA in patients in extremis (no pulse, no blood pressure) and the use of REBOA in patients with two major bleeding sites.

Conclusions: Consensus was reached on indications, contra indications, physiological parameters for patient selection for REBOA and early femoral access. The panel did not reach consensus on the use of REBOA in patients in pre-hospital settings, patients in extremis (no pulse, no blood pressure) and in patients with 2 or more major bleeding sites. Further research should focus on the indications of REBOA in pre hospital settings, patients in near cardiac arrest and REBOA inflation times.

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Introduction

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an adjunct to sustain the circulation until definitive surgical or endovascular repair [1]. Three recent systematic analysis have helped to consolidate a disparate evidence base in patients with severe traumatic or non-traumatic haemorrhage [2–4]. A large cohort study on the use of REBOA at a single tertiary care facility in these patients report that REBOA is a minimally invasive alternative to emergency department thoracotomy with aortic cross-clamp to temporize non-compressible torso haemorrhage and obtain proximal control in both traumatic and non traumatic

causes of haemorrhage [5]. But since optimal patient selection and a clear mortality benefit has yet to be demonstrated, the REBOA concept is still not fully embedded in most hospitals. Furthermore, the pioneering use of this haemorrhage control adjunct in the prehospital phase, despite early promising results [6,7], has not been widely adopted. Recent terrorist threats in western countries have contributed to an increased awareness of the value for advanced bleeding control in the earliest phase after injury, suggesting that the potential utilization of REBOA in this setting warrants examination [8]. In particular, there is a need to focus research on the differences between the main indications for REBOA; trauma and non-trauma related major haemorrhage, including ruptured abdominal aortic aneurysm (rAAA). The outcome of this study contributes to the clinical practice guidelines and reviews [2–4] that have been recently published by Pasley et al (the Joint Trauma System Clinical Practice Guideline 38 (JTS CPG 38) [9], Cannon et al [10] and Brenner et al (Joint statement from

* Corresponding author: Department of Surgery, Alrijne Hospital, Simon Smitweg 1, 2353 GA, Leiderdorp, the Netherlands.

E-mail address: blsborgervanderburg@alrijne.nl (B.L.S. Borger van der Burg).

the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP) regarding the clinical use of REBOA [11].

The primary aim of this paper is to establish consensus on the indications and contra indications for the use of REBOA in trauma and non-trauma patients based on the existing evidence and expertise.

Methods

The Delphi technique is well suited for consensus-building by using a series of questionnaires to collect data from a panel of selected subjects [12]. An international three-round Delphi consultation was conducted.

Consensus definition

The definition of consensus was established before data analyses. The questions with >70% agreement (positive or negative) and > 70% response rate met the definition of consensus. This threshold is similar to that used in other studies [12–14]. Using the Delphi method, we report on the indications for REBOA in hemodynamic unstable trauma and vascular patients.

Delphi panelists

Criteria used to select experts included expertise in the field of treating major trauma in civilian and military setting, treatment of ruptured aneurysms and vascular injuries and scientific output on the subject of endovascular resuscitation and trauma management. The (principal) investigators were asked to provide a list of potential panel members based on previously described parameters. In total 52 experts were identified and the level of expertise was discussed within the study group. Participants were invited by email receiving the link to the survey using the SurveyMonkey® platform (unique for each participant), an online survey system. The Delphi Consensus panel consisted of international civilian and military care providers and included interventional radiologists, emergency physicians, trauma and vascular surgeons. Contributing panel members were asked to confirm their expertise in the field of non compressible torso haemorrhage (NCTH), case load per annum and the use of REBOA in civilian or military setting.

Contents of the Delphi consultation: first, second and third round

For the first round in the Delphi process we created a structured questionnaire after extensive review of the literature. The initial questionnaire was based on a questionnaire used at the Endovascular Resuscitation and Trauma Management (EVTM) symposium of 2017 in Orebro, Sweden [15]. The first questionnaire consisted of 19 multiple choice questions. A structured questionnaire in round 1 is an accepted modification of the Delphi format [16]. After the first round investigators analyzed the answers of round 1 where the threshold for consensus was not reached. A second questionnaire of 19 multiple choice questions was created using the results of round 1 with the purpose to further specify the answers of the panelists. Areas of disagreement and agreement were identified. A third and final questionnaire of 22 multiple choice questions was created, based on the answers provided in round 2 where consensus was not reached. The experts were given feedback on questions where no consensus was reached and were asked to revise his/her judgments or to specify the reasons for remaining outside the consensus. Since compared to the previous round, only a slight increase in the degree of consensus was expected [12], only topics were addressed where the threshold of consensus was within reach. It is believed that during this process

the group will converge towards the "correct" answer [17]. Non responders in rounds 1 and 2 were excluded from this final round. Finally, the process was stopped after predefined stop criteria. These were: after three rounds or earlier when negative or positive consensus was achieved. The questions with >70% agreement (positive or negative) and > 70% response rate met the definition of consensus.

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS®, Version 24, IBM Corporation, Armonk, New York). All responses of the panelists were registered in an electronic data file provided by the SurveyMonkey® platform. For all statistical analyses, a p-value equal or less than 0.05 was considered significant.

Results

In the first round 38 panel members (38/52, 73.1%), responded to the questionnaire, with 36 (36/38, 94.7%) panel members completing the survey in full. The panel members consisted of 2 emergency physicians (2/38, 5.3%), 3 interventional radiologists (3/38, 7.9%), 12 vascular surgeons (12/38, 31.6%) and 21 trauma surgeons (21/38, 55.3%). The region of their practice was in 1 case from the UK (1/36, 2.8%), 2 from Asia (2/36, 5.6%), 3 from South America (3/36, 8.3%), 3 panel members practice in Africa (3/36, 8.3%), 12 panel members in North America (12/36, 33.3%) and 15 from Europe (15/36, 41.7%). The practices of the panel members were best described as Non Governmental Organization (NGO) (1/36, 2.8%), Armed Forces (3/36, 8.3%), Level 2 Trauma Centers (4/36, 11.1%) and Level 1 Trauma Centers (32/36, 88.9%). In round 2 of the survey 43 panel members responded (43/52, 82.7%). In the final round 37 panel members responded (37/43, 86%), previous non responders were excluded (n = 9). Only 1 panel member responded to 1 round, 14 responded to 2 rounds and 28 panelists responded to 3 out of 3 rounds. In total 39/46; 84.7% of panel members responded to the questions regarding their level of expertise. The panel members were experienced in the treatment of NCTH in 39/39; 100%, the case load per annum of NCTH was 0–5 in 8/39; 20.5%, 6–10 in 9/39; 23.1% and >10 cases per annum in 22/39; 56.4%. All responding panel members had used REBOA in civilian or military setting 32/32; 100%.

Indications and contraindications for REBOA

Location of procedure

The expert panel reached consensus that REBOA can be used in austere military setting, emergency departments, operating rooms and intensive care units, but disagrees with the statement that REBOA is feasible in the pre hospital setting (20/36, 55.6%).

Location of bleeding site

Panel members reached consensus that REBOA is indicated in the following patient populations: traumatic abdominopelvic hemorrhage, hemorrhage arising from a ruptured aneurysm, patients with severe post partum hemorrhage (PPH), exsanguination secondary to iatrogenic injuries (for instance during pelvic surgery, cancer or vascular surgery) and in patients with severe gastro-intestinal bleeding considered for emergency endoscopic treatment or angiographic embolization (Table 1).

The panel reached consensus that bleeding sites proximal to the left subclavian artery (LSA) and bleeding sites originating in the neck are contra indications for the use of REBOA; 85.0% (33/36). No consensus was reached that REBOA is contra indicated for bleeding

Table 1

Overview of responses regarding potential indications, settings for use of REBOA, physiological parameters for patient selection and bleeding sites.

Potential indications for REBOA	Number of panel agreeing	Consensus reached
01. traumatic abdominopelvic hemorrhage	36/36, 100%	Yes
02. ruptured aneurysm patients	33/36, 91.7%	Yes
03. post partum hemorrhage	33/36, 91.7%	Yes
04. severe gastro-intestinal bleeding	35/41, 85.4%	Yes
05. exsanguination secondary to iatrogenic injuries	34/36, 94.4%	Yes
Potential settings for REBOA use	Number of panel agreeing	Consensus reached
06. combat injury in austere settings	35/36, 97.2%	Yes
07. austere military environment	28/36, 77.9%	Yes
08. pre-hospital environment	20/36, 55.6%	No
09. emergency department (ED)	36/36, 100%	Yes
10. operating room (OR)	34/36, 94.4%	Yes
11. intensive care unit (ICU)	26/36, 72.2%	Yes
Physiologic parameters for potential REBOA use	Number of panel agreeing	Consensus reached
12. trauma patients or suspected aneurysm patients with an initial systolic blood pressure <90 mmHg who do not respond at all to initial fluid or blood product administration	38/40, 95.0%	Yes
13. any trauma victim with an ATLS® class III hypovolemic shock	12/36, 33.3%	No
14. any trauma victim with an ATLS® class IV hypovolemic shock	33/40, 82.5%	Yes
15. suspected aneurysm patients with an initial systolic blood pressure <90 mmHg who do not respond at all to initial fluid or blood product administration	28/36, 77.8%	Yes
16. ruptured aneurysm patients with a systolic blood pressure <90 mmHg	33/37, 89.2%	Yes
17. patients in extremis (no pulse, no blood pressure)	11/36, 30.6%	No
18. trauma patients or suspected aneurysm patients with an initial systolic blood pressure <90 mmHg who respond transiently to initial fluid or blood product administration	23/40, 57.5%	No
Bleeding site: use of REBOA contra indicated	Number of panel agreeing	Consensus reached
19. major bleeding in the neck	32/37; 86.5%	Yes
20. major bleeding proximally of LSA	34/40; 85%	Yes
21. major bleeding distally of LSA	21/37; 56.8%	No

sites located in the chest distally from the LSA. In patients with 2 major bleeding sites (double jeopardy) no consensus was reached on whether in these instances REBOA is indicated or contra indicated (Table 2).

Emergent resuscitative thoracotomy and REBOA

In round 1, the expert panel was asked whether they agreed that emergent resuscitative thoracotomy and REBOA have largely identical indications. 16.7% (6/36) of panel members agreed, 19.4% (7/36) regarded the indications for both interventions completely different with 55.6% (20/36) agreeing that the decision for either should be individualized. In round 2 we asked whether the panel members agreed that emergent resuscitative thoracotomy and REBOA have largely identical indications, but that the decision for either should be individualized in each instance. 23/40; 57.5% of experts agreed to that statement. In round 3 we asked whether the panel members could agree to the statement that the indications for emergent resuscitative thoracotomy and REBOA are different and the decision for either should be individualized in each instance. 26/37; 70.3% of panel members agreed, resulting in consensus.

Table 2

In unstable patients with 2 major bleeding sites: which is not a contra indication for REBOA?

In unstable patients with 2 major bleeding sites: which is not a contra indication for REBOA	Number of panel agreeing	Consensus reached
01. major bleeding in the neck	10/37; 27.0%	No
02. major bleeding in the chest	11/37; 29.7%	No
03. associated intracranial injury / bleeding	11/37; 29.7%	No
04. none of the above	13/37; 35.1%	No

Physiological parameters

The physiological parameters to select patients for REBOA use are trauma victims and (suspected) ruptured abdominal aneurysm patients with an initial systolic blood pressure of <90 mmHg who do not respond at all to initial fluid or blood products and trauma victims with an ATLS® class IV hypovolemic shock [18]. Patients in extremis (no pulse, no blood pressure) should not be considered for REBOA with 25/36; 69.4% of panel members agreeing. Although the panel disagreed with the statement that trauma victims and suspected ruptured aneurysm patients with an initial blood pressure of <90 mmHg who are transient responders to fluid or blood products are REBOA candidates, they agree that REBOA should be considered (30/37; 81.1%) in this patient groups. The panel did not support the statement that trauma victims with a systolic pressure >90 mmHg, but with a mechanism of injury suspicious for high early bleeding risk (severe pelvic fracture, positive FAST exam) should be eligible for REBOA (7/36; 19.4%). These categories of patients are candidates for early femoral access (28/40; 70.0%).

Occult traumatic brain injury identified on emergent head imaging in the absence of altered pupillary exam, lateralizing signs, depressed skull fracture or penetrating injury to the skull should not be considered a contraindication for REBOA. The panel members reached consensus on this statement; 80.6% (29/36).

Vascular access

Femoral artery access is a precursor for potential REBOA use, but does not mandate subsequent REBOA use (Table 3). In case of early femoral artery access a 5 Fr (15/36; 41.7%) or 7 Fr (15/36; 44.4%) introducer sheath was recommended. Panel members stated that

Table 3
Indications for early femoral access.

Early femoral access is indicated in	Number of panel agreeing	Consensus reached
01. any trauma victim with an ATLS® class III or IV hypovolemic shock	37/40; 92.5%	Yes
02. trauma victims with an initial systolic blood pressure <90 mmHg who do not respond at all to initial fluid or blood products	31/36; 86.1%	Yes
03. trauma victims with an initial systolic blood pressure <90 mmHg who respond transiently to initial fluid or blood products	31/40; 77.5%	Yes
04. suspected ruptured aneurysm patients with blood pressure <90 mmHg	29/36 ; 80.6%	Yes
05. patients in extremis (no pulse, no blood pressure)	32/40; 80.0%	Yes
06. trauma victims with a systolic pressure >90 mmHg, but with a mechanism of injury suspicious for high early bleeding risk (severe pelvic fracture, positive FAST exam)	28/40; 70.0%	Yes

trauma surgeons (26/36; 72.2%) or vascular surgeons (24/36; 66.7%) should perform the REBOA procedure, but agreed that REBOA can be safely and effectively performed in a variety of settings and by providers of various clinical background, provided that they have appropriate training and local protocols for use (30/36; 83.3%).

Inflation times for REBOA

Zone 1 REBOA

Regarding inflation times for aortic occlusion in Zone 1 of the aorta, it is not recommended that inflation time (full REBOA) exceeds more than 30 min with 87.5% (35/40) of panel members agreeing. Panel members were divided on whether the inflation times for aortic occlusion in Zone 1 of the aorta should be limited (15/40; 37.5%) or not (25/40; 62.5%) if the patients remained unstable despite aggressive efforts.

Zone 3 REBOA

Regarding inflation times for aortic occlusion in Zone 3 of the aorta, it is not recommended that inflation time (full REBOA) exceeds more than 60 min (28/37; 78.4%). Inflation time in Zone 3 of the aorta should not be limited if the patients remains unstable despite aggressive efforts (28/40; 70.0%).

Intermittent and partial REBOA

According to the panel, the most viable tool in prolonging the potential use of REBOA while attempting to avoid the dangers of distal ischemia, is early partial occlusion (transitioning to partial occlusion after a short period of full occlusion) (34/40; 85.0%). Intermittent occlusion was seen as a viable tool for prolonging the use of REBOA by a minority of panel members (12/36; 33.3%). Intermittent REBOA is considered an alternative for partial occlusion when partial occlusion does not secure distal perfusion (33/36; 91.7%).

Discussion

Panel members reached consensus that REBOA is potentially indicated in patient populations that are consistent with the beneficial effect of REBOA found in the recently published review and meta analyses by Borger van der Burg et al [4] and patients

described in the joint statement from the ACS COT and ACEP and JTS CPG 38. Our panel considered that patients in extremis (no pulse, no blood pressure) are no candidates for REBOA, but should undergo early femoral access. This is in contradiction to both the joint statement from the ACS COT and ACEP and JTS CPG 38 where there is a role for REBOA in patients arriving in arrest from injury due to presumed life-threatening haemorrhage below the diaphragm. The JTS CPG 38 states that blunt trauma patients and/or patients with penetrating trauma to the abdomen/ pelvis in traumatic who have no palpable carotid pulse but have any organized electrocardiography rhythm or cardiac contraction on ultra sound could be candidates for REBOA in case of clinical response to ATLS ® resuscitation protocols. Teeter et al [19] compared patients in arrest who received aortic occlusion with REBOA or resuscitative thoracotomy for total cardiac compression time. They found that total duration of interruptions of cardiac compressions is shorter for patients receiving REBOA versus resuscitative thoracotomy before and during resuscitation with aortic occlusion. Although not powered for outcomes, two patients in the REBOA group survived to discharge, with no survivors in the resuscitative thoracotomy group. There was an additional trend toward survival past the emergency department for REBOA (9/22; 40.9%) compared with resuscitative thoracotomy (3/28; 10.7%).

Our panel states no indication for pre hospital use of REBOA but sees a role for REBOA in austere (military) settings. Therefore, we presume that the use of REBOA in prehospital, military environment could be indicated for selected cases. The prehospital military potential is strengthened by the study of Manley et al, which presents a case series of wartime injured patients at an austere location where REBOA was used in patients with torso gunshot or fragmentation wounds, hemo-peritoneum, and class IV shock. Hand-held ultrasound was used to facilitate 7Fr femoral sheath access and REBOA placement, resulting in immediate normalization of blood pressure and patients surviving to achieve transport to the next echelon of care in stable condition [6].

Our panel members reached consensus that trauma surgeons or vascular surgeons should perform the REBOA procedure, but agreed that REBOA can be safely and effectively performed in a variety of settings and by providers of various clinical background, provided that they have appropriate training and local protocols for use. This is consistent with the joint statement from the ACS COT and ACEP that REBOA should be performed by an acute care surgeon or an interventionalist (vascular surgeon or interventional radiologist) trained in REBOA. Borger van der Burg et al have recently published on training of a variety of personnel with limited or no previous endovascular experience on REBOA placement [20,21]. They found that a comprehensive theoretical and practical training program using a task training model or a live tissue-simulator hybrid porcine model can be used for femoral access and REBOA placement training in medical personnel and military medical personnel without prior ultrasound or endovascular experience, and that higher level of training reduced procedure times. Matsumura et al found that early arterial access for resuscitative endovascular balloon occlusion of the aorta is related to improved survival in trauma [22]. The “Prompt and Rapid Endovascular Strategies in Traumatic Occasions” (PRESTO) as described by Matsumoto et al entails that a femoral arterial sheath will be rapidly placed before groin swelling occurs during the primary survey. This provides a readily available access route for REBOA. The sheath can also be a route for embolization, arterial pressure monitoring, as well as transfusion lines [23]. This is consistent with our consensus that early femoral access should be considered in any hemodynamically unstable trauma or suspected ruptured aneurysm patients and even in trauma victims with a systolic pressure >90 mmHg,

but with a mechanism of injury suspicious for high early bleeding risk (severe pelvic fracture, positive FAST exam). The ACS COT and ACEP statement advises that Zone 1 REBOA should only be performed if the anticipated time to start of operation is less than 15 min which is half the time of what our panel members agreed on. Our panel agreed on a maximal inflation time of 30 min in Zone 1, however 15 min was not an option in our survey. JTS CPG 38 states that Zone 1 REBOA may be placed for 30–60 min and Zone 3 REBOA may potentially stay up for longer period of time if necessary. Panel members were divided on whether the inflation times for aortic occlusion in Zone 1 of the aorta should be limited if the patients remained unstable despite aggressive efforts. Inflation time in Zone 3 of the aorta should not be limited if the patients remains unstable despite aggressive efforts. The ACS COT and ACEP statement does not state a specific inflation time in zone 3, but describes that REBOA in Zone 3 may be tolerated for longer periods of time than Zone 1 REBOA and as such may be used as an immediate adjunctive bleeding control prior to angioembolization, preperitoneal packing or exploration. According to the panel, the most viable tool in prolonging the potential use of REBOA while attempting to avoid the dangers of distal ischemia is early partial occlusion (transitioning to partial occlusion after a short period of full occlusion). The ACS COT and ACEP statement reports that partial balloon inflation at either location (Zone 1 or 3) may prolong the interval between injury and successful definitive treatment; however, they correctly state that this is not well studied. Intermittent occlusion was seen as a viable tool for prolonging the use of REBOA by a minority of panel members. Intermittent REBOA is considered an alternative for partial occlusion when partial occlusion does not secure distal perfusion [24]. Kuckelman [25] reports that intermittent REBOA can maintain supra-celiac haemorrhage control while decreasing distal ischemia in a swine model. Prolonged survival times, decreased acidosis, and lower resuscitation requirements indicate that this technique could potentially extend Zone 1 REBOA deployment times. Besides the benefit of minimally invasive proximal bleeding control with the REBOA technique, there are negative studies that fail to support the presumed beneficial effect of REBOA. Norii et al analyzed observational prospective data from the Japan Trauma Data Bank (2004–2011) to compare the mortality between adult patients who received a REBOA with those who did not. They concluded that REBOA treatment is associated with higher mortality compared with similarly ill trauma patients who did not receive a REBOA [26]. Recently Joseph et al published a nationwide analysis of REBOA in civilian trauma patients. A case controlled retrospective analysis of the 2015–1026 American College of Surgeons data set containing 593,818 patients compared 140 patients in the REBOA group with 280 matched patients. They concluded that patients in the REBOA group had a higher mortality rate compared with the matched non REBOA patients. Joseph et al conclude that there is a need for a concerted effort to clearly define when and in which patient population REBOA has benefit [27]. The findings of Norii and Joseph warrants further assessment in prospective studies. There are limitations to this study. Using a modified Delphi method is an accepted way to provide level 5 evidence. This being the lowest level of evidence, further research from registries and prospective studies should be encouraged. Since the REBOA concept is still relatively new, the experience with REBOA is diffuse and limited. Although the response rate is high, not all selected experts responded to every single survey.

Conclusions

Our expert panel reached consensus on indications, contra indications, physiological parameters for patient selection for the

use of REBOA and early femoral access. There was no consensus on the use of REBOA in patients in the pre-hospital setting, patients in extremis (no pulse, no blood pressure) and in patients with 2 or more major bleeding sites. Further research should focus on the indications of REBOA in pre hospital settings and use of REBOA in austere military setting, patients in (near) cardiac arrest and REBOA inflation times.

Disclaimer

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the Department of Defense, Dutch or United States government. Several authors are employees of the Dutch or United States government.

Conflict of interest statement

B.L.S. Borger van der Burg, B. Kessel, J.J. DuBose, T.M. Hörer and R. Hoencamp report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

Contribution of the authors

B.L.S. Borger van der Burg, B. Kessel and R. Hoencamp prepared the study set-up. B.L.S. Borger van der Burg, B. Kessel, T.M. Hörer, J. J. DuBose and R. Hoencamp selected the panelists and constructed the questionnaires, B.L.S. Borger van der Burg performed the study and collected the data. Borger van der Burg, B. Kessel, T.M. Hörer, J.J. DuBose and R. Hoencamp prepared the manuscript. B.L.S. Borger van der Burg the tables. Borger van der Burg, B. Kessel, T.M. Hörer, J.J. DuBose and R. Hoencamp contributed to the final version of the paper.

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