Egyptian Journal of Anaesthesia

ISSN: (Print) 1110-1849 (Online) Journal homepage: https://www.tandfonline.com/loi/teja20

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To cite this article: Waleed Hamimy, Magdy Khalil, Mohamed Ismail, Wafaa Taha Salem, Akram Muhammad Fayed, Mohamed Abd-El Khalek, Islam Mussad, Hans Djurberg, Abdul-Aziz Al-Khoja, Walid Al-Yafi, Adel Shabacy, Samer Soliman, Akram Naguib, Hassan Al-Zamk, Mohamed Maan, Maizer Khalaf, Nader Honjul, Nizar Al-Zoghaiby, Mohamed Abou El-Ela, Yassir Kafafi, Hesham Zeyada, Khaled Maher & Mohamed Samir Gad (2011) Waxy-Maize HES 130/0.4; evidence based clinical decisions, Egyptian Journal of Anaesthesia, 27:3, 197-202, DOI: 10.1016/j.egja.2011.04.009

To link to this article: https://doi.org/10.1016/j.egja.2011.04.009

Published online: 17 May 2019.

Egyptian Journal of Anaesthesia (2011) **27**, 197–202

Egyptian Society of Anesthesiologists

Egyptian Journal of Anaesthesia

www.elsevier.com/locate/egja
www.sciencedirect.com

Review Article

Waxy-Maize HES 130/0.4; evidence based clinical decisions

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Received 14 March 2011; accepted 17 April 2011
Available online 28 June 2011

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Peer review under responsibility of Egyptian Society of Anesthesiologists.
doi:10.1016/j.egja.2011.04.009

KEYWORDS

Hes 200/0;
Hes 130/0.4;
Anesthesia;
ICU

Abstract The profile of an ideal volume substitution solution can be defined by volume effect and safety. The volume effect should be stable and reliable, offer a constant plateau effect and be easily controllable. Many in depth characteristics has been offered by recognized societies [1] and includes: no tissue storage, no plasma accumulation, no influence on haemostasis, no influence on the immune system, no infectivity, no antigenicity, no allergenic potential, no proinflammatory properties, no toxicity, teratogenity or mutagenity, no influence on diagnostic tests, good compatibility with other medication, good tolerance, and complete elimination. Research has shown that it is possible to meet these objectives in the development of hydroxyethyl starches (HES) by optimizing the combination of concentration, the molecular weight, the degree and pattern of substitution. A new starch (HES 130/0.4) has therefore been developed. This new generation of HES offers the same volume effect and duration as the previous standard HES 200/0.5, yet with more favorable pharmacological characteristics and an improved safety profile. The following article is a collection of experts' opinion from different recognized universities, hospitals and healthcare organizations about the evidence based clinical decisions when using Waxy-Maize HES 130/0.4 (Voluven®) in various clinical situations.

Contents

1. When should an anesthetist consider Waxy-Maize HES 130/0.4 usage and why?

Waxy-Maize HES 130/0.4 should be considered for prophylaxis and treatment of hypovolaemic cases being effective plasma volume expander giving 100% volume expansion and with 4–6 plateau effect [2] compared to crystalloids which deliver only 20–30% volume expansion with 30 min duration of expansion. Along with being effective, Waxy-Maize HES 130/0.4 has an excellent safety profile at high dose application reaching 50 mg/kg bw/day in all age groups including children [3–8]. Its safety has been proved also in repeated administration [7], and with a highly recognized amount of evidence based literature that reached more than 180 publications along with proven safety records in more than 30 million patients.

2. When should an intensivist consider Waxy-Maize HES 130/0.4 usage and why?

In addition to the previous points, Waxy-Maize HES 130/0.4 would help in reaching an optimized tissue oxygenation and improved microcirculation when compared to crystalloids as established in Lomivorotov [9] and Dubin [10]. Waxy-Maize HES 130/0.4 also helps in reducing inflammatory response

and endothelial activation along with the recognized characteristic of the capillary ceiling properties of Waxy-Maize HES 130/0.4 in cases of capillary leakage syndrome with comparison to different fluid regimens [11–21] among which is albumin which appeared to be inferior to Waxy-Maize HES 130/0.4 which reduced incidence of pulmonary oedema and improved of the APACHE II score as established by Palumbo [22]. The clear advantage in reduced total fluid administration when using Waxy-Maize HES 130/0.4 also helps in guarding against intra-abdominal hypertension with comparison to crystalloids as in Vidal [23].

3. What are the other benefits for Waxy-Maize HES 130/0.4 usage rather than being a plasma expander?

Waxy-Maize HES 130/0.4 can assist clinician in achieving better tissue oxygenation than crystalloids through improvement of microcirculation while reducing the total fluid administration [9,10,24]. Another benefit is the lower inflammatory response with Waxy-Maize HES 130/0.4 in comparison to crystalloids and albumin by lowering the inflammatory response and endothelial activation [11–21]. The improvement of pulmonary functions in comparison to albumin has been established in favor of Waxy-Maize HES 130/0.4 in septic patients [22].

4. What are the advantages that Waxy-Maize HES 130/0.4 brings to clinical practice over older starches?

With Waxy-Maize HES 130/0.4, there is no plasma accumulation even in repetitive high doses as established by Waitzinger [25] and Ellger [5]. Waxy-Maize HES 130/0.4 has very minimal effect on blood coagulation and many evidence based assessment established that with Waxy-Maize HES 130/0.4 there is less blood loss in comparison to Pentastarch which was reviewed by Kozek-Langenecker [26]. Waxy-Maize HES 130/0.4 has a better renal profile even in severe renal impairment even at creatinine clearance close to 15 ml/min as established by Jungheinrich [27]. Waxy-Maize HES 130/0.4 has a maximal daily dose of 50 ml/kg bw/day which is by far higher than older starches such as Hetastarch (20 ml/kg bw/day) and Pentastarch (33 ml/kg bw/day). The FDA has approved Waxy-Maize HES 130/0.4 in treatment and prophylaxis of hypovolaemia in adults, pediatrics and neonates in December 2007 [28].

5. What should be the consensus of Waxy-Maize HES 130/0.4 usage in comparison to albumin and crystalloids?

Albumin has been a choice for treatment of hypovolaemia in critically ill patients until the 1998 Cochran review [29] showed increased mortality when compared to isotonic saline. Then the SAFE study [30] showed that both have the same mortality rates in the ICU settings. Waxy-Maize HES 130/0.4 has capillary sealing properties with less possibility of pulmonary edema than albumin as established by Palumbo [22]. When taking into consideration the high cost of albumin products, Waxy-Maize HES 130/0.4 appears to be more cost-effective than albumin. Another advantage is that Waxy-Maize HES 130/0.4 has a quicker infusion rate than albumin (25 ml/min vs. 5 ml/min) [31]. The availability of Waxy-Maize HES 130/0.4 is better than albumin solutions which have been proved through history of shortage of albumin supply due to donors' restrictions. The handling of albumin solution is requiring special storage care to avoid alteration of the protein nature of the solution while HES products do not require such restrictions.

In comparison with crystalloids Waxy-Maize HES 130/0.4 has a volume expansion of 100% while crystalloids have only 20–30% effect. The plateau effect of Waxy-Maize HES 130/0.4 with duration of 6 h is more clinically favorable in comparison to crystalloids which have duration of expansion that lasts only 30 min even with hypertonic saline. Waxy-Maize HES 130/0.4 maintains hemodynamics with less volume than crystalloids lowering the morbidity associated with excess volume and with its rheological properties it improves microcirculation and tissue oxygenation resulting in better organ function, while crystalloids worsen it [9,10]. Waxy-Maize HES 130/0.4 reduces inflammatory response and capillary leakage resulting in less edema than different fluid regimens [11–22].

Waxy-Maize HES 130/0.4 is more effective than crystalloids in reducing the incidence of hypotension if used as preloading fluid before spinal anesthesia as established by Sucre [32], Ko [33], Barbe [34], Madi-Jebara [35], and Siddik [36].

6. Among starches used in fluid therapy regimens, why Waxy-Maize HES 130/0.4 considered a class of its own?

Waxy-Maize HES 130/0.4 holds the best evidence based medicine among all starches: 10 years of clinical experience, 180 publications, and more than 30 million patients' usage.

7. Why should we consider Waxy-Maize HES 130/0.4 for a critically ill patient although there are some reports indicating increased risk of acute renal injuries in septic patients when using older starches?

Safety of Waxy-Maize HES 130/0.4 on renal functions has been proved in a lot of critically ill patients in more than 20 clinical trials [7,8,27,37–47].

The report of increased AKI is associated with the use of older starches such as Pentastarch 10% (hyperoncotic) and is mostly related to its accumulation [48]. While Waxy-Maize HES 130/0.4 proved to have no accumulation even with renal impairment: with comparison to older starches as in Jungheinrich [27]. Clinicians should always look for the right HES: Waxy-Maize 130/0.4 with reduced molecular weight and reduced molar substitution.

8. What is the role of Waxy-Maize HES 130/0.4 in guarding against intra abdominal hypertension and what is the expected benefit in the ICU setting?

Waxy-Maize HES 130/0.4 reduces total administration of resuscitating fluids (reduce positive fluid balance). A high amount of resuscitating fluids is the major risk factor for increased IAH as established by Vidal [23]. In the ICU as referred by Malbrain [49], patients with IAH (>12 mm) leads to a mortality rate of 38.8% while patients with no IAH had mortality rates of 22.2%.

9. According to the American practice, crystalloids should be the right choice in septic patients in the ICU, why should we consider Waxy-Maize HES 130/0.4 for these patients?

There is no contra-indication of using Waxy-Maize HES 130/0.4 (as a colloid) in any American guidelines. United States experience with Waxy-Maize HES 130/0.4 started very recently: Waxy-Maize HES 130/0.4 FDA approval was in December 2007 [28] while the actual usage started late 2008. There is an increased interest in using Waxy-Maize HES 130/0.4 in the states nowadays with matching reports of its safety and efficacy to the worldwide experience that started more than 10 years ago when Waxy-Maize HES 130/0.4 was launched in Europe. Voluven's advantages in septic patients includes: capillary ceiling properties in capillary leakage syndrome [11–21] reduction of the total fluid administration which will guard against IAH in comparison to crystalloids [23], reduced incidence and severity of oedema [22].

10. There are some publications referring to Waxy-Maize HES 130/0.4 as the right choice for routine preloading before spinal anesthesia while there are some other publications doubting the principle of pre-lauding itself. What do you think is the benefit of using Waxy-Maize HES 130/0.4 in such cases and is it justified to consider Waxy-Maize HES 130/0.4 as the right choice fluid?

There are about 6 clinical trials showing that Waxy-Maize HES 130/0.4 is more efficient compared to crystalloids to prevent hypotension after spinal anesthesia during C-Section [32–36]. And there is an ongoing trial named the CAESAR trial also evaluating Waxy-Maize HES 130/0.4 in such cases [50]. The debate of prelaude or not is yet not conclusive, but there is a pile of evidence supports the prevention of hypotension induced by Spinal Anesthesia when pre-lauding with Waxy-Maize HES 130/0.4 especially that you use half (or even one-third) the amount of crystalloids. Waxy-Maize HES 130/0.4 was referenced as "The right choice for routine Preloading before spinal anesthesia" [33].

11. What is the current clinical experience of Waxy-Maize HES 130/0.4 in pediatric surgery?

Seven published clinical trials studying Waxy-Maize HES 130/0.4 in pediatrics up to 50 ml/kg/day including cardiac surgery and compared to albumin [6,51–56].

12. What are the major benefits of Waxy-Maize HES 130/0.4 usage in cardiac surgery?

Benefits in cardiac surgery including using Waxy-Maize HES 130/0.4 as priming solution with comparison to crystalloids and albumin has been established by many authors such as Hengo [57]:

- Well characterized plasma volume expansion.
- Large volume (50 ml/kg bw/ day).
- Minor effects on haemostasis.
- Minor influence on renal function.
- Relative rapid elimination.
- Reduction of endothelial cell activation and inflammatory response.
- Minimal risk of anaphylactic reactions.

13. Can Waxy-Maize HES 130/0.4 be considered in burn patients?

In Sudhakar [58] "Waxy-Maize HES 130/0.4 vs. Ringer's Lactate", and in Shen [59] results indicate that the optimum quality of circulating blood replenishment and elimination of hypovolaemia are obtained by the use of hydroxyethyl starch 130/0.4 that offers advantages as the rate of blood concentrations and maintenance of volume levels as well as increasing oxygen delivery, resulting in quicker recovery from shock and improvement of burn wound trophism.

14. Is it safe to use Waxy-Maize HES 130/0.4 in transplant surgery?

Waxy-Maize HES 130/0.4 has been used in two Kidney transplant trials (Blasco [40], Pavlidis [45]) and one liver transplant trial (Mukhtar [8]) vs. albumin and it was recommended for routine use.

15. Why is Waxy-Maize HES 130/0.4 better than potato starches even if tetra starch? Does the type of raw material make that difference?

The superiority of Waxy-Maize HES 130/0.4 is obtained from:

- Differences in raw materials.
- Differences in molecular weight, molar substitution and substitution pattern.
- Differences in amylose content and degree of branching (higher amylose/lower branching in potato-starches) [60,61].
- Difference of phosphate content (higher in potato-starches) [62].
- Incidence of hyperbilirubinemia with potato-starches [63].
- Higher number of evidence based literatures in comparison to potato starches which are:
- Very few (mostly in vitro studies).
- Not comparing safety with colloids such as Waxy-Maize HES 130/0.4 in clinical settings.

16. What is the incidence of anaphylactoid reactions with Waxy-Maize HES 130/0.4?

Of all colloids, hydroxyethyl starch has the lowest rate of allergic reactions documented (approx. 0.06%). Major Anaphylactoid reactions (Grade III and IV) are very rare during HES therapy (Ring and Meßmer, 1977; Laxenaire et al., 1994; Dieterich et al. 1998) [64].

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