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**ESPS Peer-review Report** 

Name of Journal: World Journal of Gastroenterology

**ESPS Manuscript NO: 9336** 

Title: An observational study of the clinical efficacy of tolvaptan for the treatment of refractory

ascites in patients with decompensated liver cirrhosis

Reviewer code: 02444774 Science editor: Gou, Su-Xin

Date sent for review: 2014-02-10 12:02

Date reviewed: 2014-02-13 23:32

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
[ ] Grade A (Excellent)	[ ] Grade A: Priority Publishing	Google Search:	[ ] Accept
[ ] Grade B (Very good)	[ Y] Grade B: minor language polishing	[ ] Existed	[ ] High priority for
[ Y] Grade C (Good)	[ ] Grade C: a great deal of	[ ] No records	publication
[ ] Grade D (Fair)	language polishing	BPG Search:	[ ]Rejection
[ ] Grade E (Poor)	[ ] Grade D: rejected	[ ] Existed	[Y] Minor revision
		[ ] No records	[ ] Major revision

#### **COMMENTS TO AUTHORS**

1. Serial data on renal parameters (e.g. potassium, urea, creatinine) should be provided, especially in patients with pre-existing renal impairment or HRS. 2. Please discuss the FDA's warning on tolvaptan that it should not be used for longer than 30 days or by patients with preexisting liver disease, such as cirrhosis. 3. Any of these patients had received paracentesis before using tolvaptan?



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Name of Journal: World Journal of Gastroenterology

ESPS Manuscript NO: 9336

Title: An observational study of the clinical efficacy of tolvaptan for the treatment of refractory

ascites in patients with decompensated liver cirrhosis

**Reviewer code:** 00039143 **Science editor:** Gou, Su-Xin

Date sent for review: 2014-02-10 12:02

Date reviewed: 2014-02-17 17:47

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
[ ] Grade A (Excellent)	[Y] Grade A: Priority Publishing	Google Search:	[ ] Accept
[ ] Grade B (Very good)	[ ] Grade B: minor language polishing	[ ] Existed	[ ] High priority for
[Y] Grade C (Good)	[ ] Grade C: a great deal of	[ ] No records	publication
[ ] Grade D (Fair)	language polishing	BPG Search:	[ ]Rejection
[ ] Grade E (Poor)	[ ] Grade D: rejected	[ ] Existed	[Y] Minor revision
		[ ] No records	[ ] Major revision

### **COMMENTS TO AUTHORS**

The manuscript report experience of an open study showing that a short-term (4-15 days) therapy with 15 mg/day of Talvoptan in refractory and decompensated cirrhotic patients is an effective and safe therapy also in patients with hepatorenal syndrome type 2 and hepatocellular carcinoma. FDA point out that vasopressin V2-receptor blockade with Talvoptan could not be used in patients with liver disease because it can cause liver injury. On the basis of this consideration, Authors should report this issue in the Introduction and in the Results they have to show the values of transaminases before and after the introduction of Talvoptan proving that this dosage and length of therapy do not affects liver function.



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**ESPS Peer-review Report** 

Name of Journal: World Journal of Gastroenterology

ESPS Manuscript NO: 9336

Title: An observational study of the clinical efficacy of tolvaptan for the treatment of refractory

ascites in patients with decompensated liver cirrhosis

**Reviewer code:** 00035193 **Science editor:** Gou, Su-Xin

Date sent for review: 2014-02-10 12:02

Date reviewed: 2014-02-24 01:25

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
[ ] Grade A (Excellent)	[ ] Grade A: Priority Publishing	Google Search:	[ ] Accept
[ ] Grade B (Very good)	[ Y] Grade B: minor language polishing	[ ] Existed	[ ] High priority for
[Y] Grade C (Good)	[ ] Grade C: a great deal of	[ ] No records	publication
[ ] Grade D (Fair)	language polishing	BPG Search:	[ ]Rejection
[ ] Grade E (Poor)	[ ] Grade D: rejected	[ ] Existed	[Y] Minor revision
		[ ] No records	[ ] Major revision

### **COMMENTS TO AUTHORS**

The current study, "An observational study of the clinical efficacy of tolvaptan for the treatment of refractory ascites in patients with decompensated liver cirrhosis" by Zheng et. al is an interesting one. This is obviously well written. I have the following comments. 1.Definition of refractory ascites based on the AASLD practice guidelines 2012 was: 1) unresponsiveness to sodium restricted diet and high dose diuretic treatment (400 mg of spironolactone and 160 mg of Furosemide) or 2) recurs rapidly after therapeutic paracentesis. Authors note that < 6 gm/day Na+ restrictions, intermittent albumin infusion (10-20 g/day), and (200 mg of spironolactone and 160 mg of Furosemide) defines refractory ascites. The reference for such should be quoted. Also , they note 3-5 L of LVP x 2 weeks define as refractory ascites. Again, reference needs to be defined, as the AASLD guideline do not endorse this definition. Is this what the authors define for their study? 2.Under the section, therapeutic protocol, authors mention .....80-160 mg/day of spironolactone. Please clarify, as Spiranolactone is available in 25, 50, and 100 mg pills in USA. Is this different in the country where the study was conducted. 3. FDA warning on Tolvaptan: should not be used for > 30 days needs to be mentioned.



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**ESPS Peer-review Report** 

Name of Journal: World Journal of Gastroenterology

ESPS Manuscript NO: 9336

Title: An observational study of the clinical efficacy of tolvaptan for the treatment of refractory

ascites in patients with decompensated liver cirrhosis

Reviewer code: 00070628 Science editor: Gou, Su-Xin

Date sent for review: 2014-02-10 12:02

Date reviewed: 2014-02-26 21:18

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
[ ] Grade A (Excellent)	[ ] Grade A: Priority Publishing	Google Search:	[ ] Accept
[ ] Grade B (Very good)	[ Y] Grade B: minor language polishing	[ ] Existed	[ ] High priority for
[ ] Grade C (Good)	[ ] Grade C: a great deal of	[ ] No records	publication
[Y] Grade D (Fair)	language polishing	BPG Search:	[ ]Rejection
[ ] Grade E (Poor)	[ ] Grade D: rejected	[ ] Existed	[Y] Minor revision
		[ ] No records	[ ] Major revision

### **COMMENTS TO AUTHORS**

This original article is an observational study of the efficacy of tolvaptan for the treatment of refractory ascites in cirrhotic patients with decompensated liver cirrhosis. - It is important to comment FDA's warning about tolvaptan in patients with liver diseases, and duration of treatment. Could explain authors more about time, dosage and MELD of these patients? How long did they treat patients with tolvaptan? - Data regarding renal function were not presented, and it is very important to know it. Please, data from serum creatinine, sodium, potassium, creatinine clearance, urine volume... etc is necessary. - As well, data regarding liver function are incompleted. MELD? - Decompensation is evaluated with abdominal circumference, urine excretion, why not did the analysed weight? - Follow-up (only one month) it is not enough for prognosis assessment. It is true that tolvaptan in refractory ascites, as in HRS is almost unexplored, but this article needs more information on clinical data and follow up.