

# 医学信息速递

## Medical Information Express

# 与抗毒蕈碱类药物和 $\beta_3$ 受体激动剂相关的不良事件

产品战略&医学与信息部

2022-08-24



传递最有价值的医学信息

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文献简介



## Adverse events related to antimuscarinics and beta-3-agonist: "real-life" data from the Eudra Vigilancedatabase 与抗毒蕈碱类药物和 $\beta_3$ 受体激动剂相关的不良事件： 来自EV数据库的“真实世界”数据

- 发表杂志：Minerva Urol Nephrol
- 出版时间：2022年6月
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ARTICLE ONLINE FIRST

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### Adverse events related to antimuscarinics and beta-3-agonist: "real-life" data from the Eudra-Vigilance database

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## 研究目的

旨在分析Eudra-Vigilance (EV)数据库中报道的AMs (抗毒蕈碱类药物) 和B3A ( $\beta_3$ 受体激动剂) 相关不良事件的真实数据。



## 研究结果

奥昔布宁、索利那新、托特罗定、非索罗定、曲司氯胺、**丙哌维林**和米拉贝隆分别报告了2313例、5129例、2483例、3523个例、787例、**621例**和7213例AEs。与索利那新(10%)、米拉贝隆(11%)和奥昔布宁(4%)相比，非索罗定(43%)和托特罗定(23%)的尿潴留更高。



## 研究方法

我们记录了截至2021年1月，EV数据库中AMs (抗毒蕈碱类药物) 和B3A ( $\beta_3$ 受体激动剂) 每种类别的AEs (不良事件) 数量和严重程度。



## 研究结论

与男性患者相比，女性患者有更高的AEs发生率。急性尿潴留的风险在八旬老人中尤其明显。

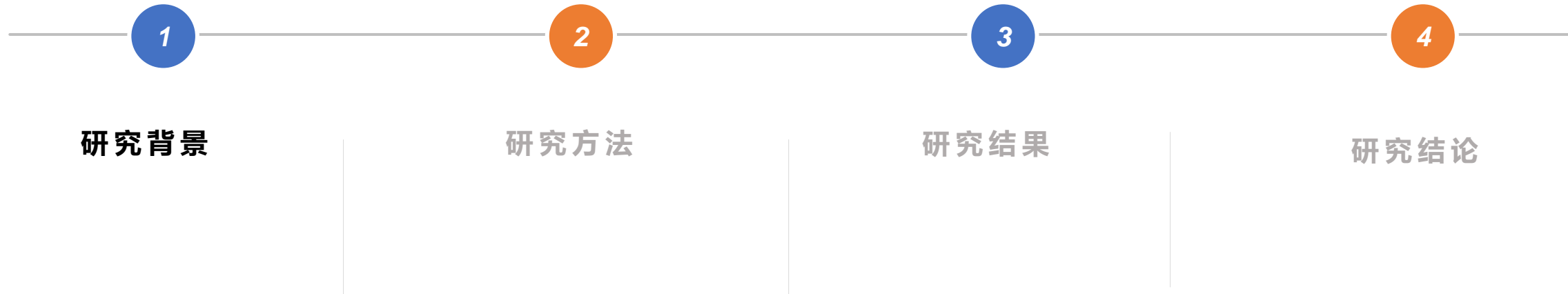


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## 文献重点内容



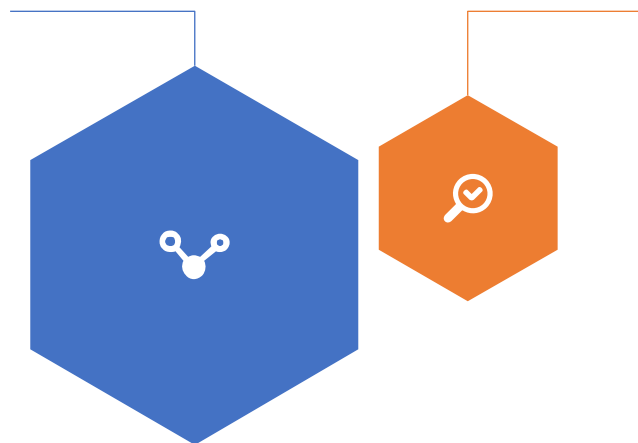
## - 文献重点内容 -





## OAB (膀胱过度活动症)

被国际尿控学会定义为一种以尿急症 (urgency)为特征的症候群，常伴有尿频和夜尿症状，伴或不伴有急迫性尿失禁，没有尿路感染或其他明确的病理改变。



## AMs 和 B3A

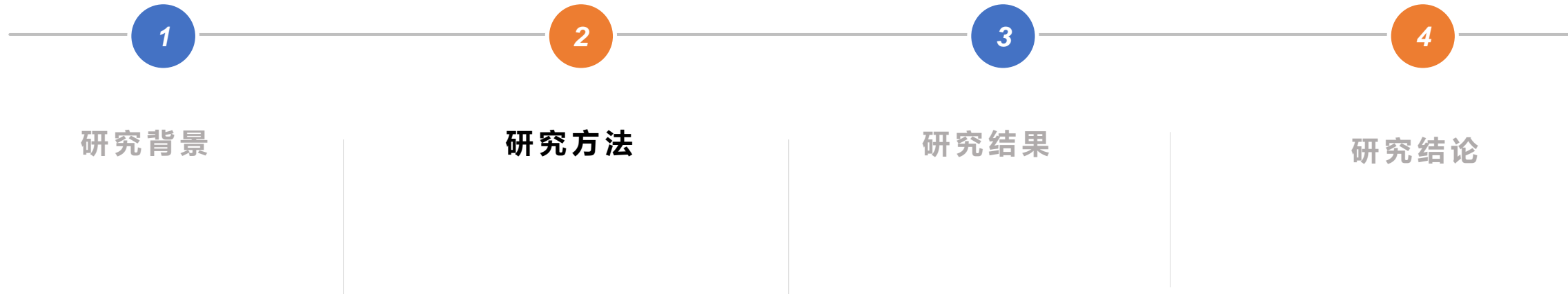
AMs和B3A是OAB的标准一线治疗药物。AMs和B3A已在几项随机临床试验中进行了测试，表明它们对治疗OAB有效，但**安全性不同**。

### 研究目的

分析Eudra-Vigilance (EV)数据库中报道的AMs (抗毒蕈碱类药物) 和B3A ( $\beta_3$ 受体激动剂) 相关不良事件的真实数据。



## - 文献重点内容 -



- 回顾性分析了EV数据库\*(www.adrreports.eu)中截至2021年1月公开和免费报告的AMs和B3A不良事件。通过EV数据库将数据提取到Microsoft Excel中，做进一步分析。并记录患者不同性别（男性、女性）和年龄（≤65、65-85、≥85岁）的AEs发生率（%）。

类别	代表药物
AMs (抗毒蕈碱类药物)	索利那新、托特罗定、非索罗定、奥昔布宁、曲司氯胺和 <b>丙哌维林</b>
B3A ( $\beta_3$ 受体激动剂)	米拉贝隆

**\*Eudravigilance (EV) 数据库：**是欧盟药物警戒数据库，由欧洲药品管理局EMA建立并维护的一个电子数据库，用于收集、管理并分析EMA已批准或正在临床试验中的药物的可疑不良反应信息。



## - 文献重点内容 -



# 研究结果：与其他药物相比，丙哌维林具有较低的高血压及尿潴留发生率

- 奥昔布宁、索利那新、托特罗定、非索罗定、曲司氯胺、**丙哌维林**和米拉贝隆分别报告了2313例、5129例、2483例、3523个例、787例、**621例**和7213例AEs。
- 女性患者口干发生比例较高，认知障碍在所有分析的药物中均不常见。
- **丙哌维林 (5%) 的尿潴留发生率低于托特罗定 (23%)、索利那新 (10%)、米拉贝隆 (10%)。米拉贝隆高血压发生率 (7%) 高于抗毒蕈碱类药物 (<1%-2%)，其中丙哌维林的高血压发生率最低 (<1%)。**

Reaction Groups		奥昔布宁	索利那新	托特罗定	非索罗定	曲司氯胺	丙哌维林	米拉贝隆
<b>Total AEs</b>		<b>2313</b>	<b>5129</b>	<b>2483</b>	<b>3523</b>	<b>787</b>	<b>621</b>	<b>7213</b>
高血压	<b>HYPERTENSION</b>	41/2313 (2%)	<b>51/5129 (2%)</b>	<b>42/2483 (2%)</b>	35/3523 (1%)	7/787 (1%)	<b>3/621 (&lt;1%)</b>	<b>529/7213 (7%)</b>
	Male	6/41 (15%)	14/51 (27%)	9/42 (21%)	9/35 (26%)	2/7 (29%)	2/3 (67%)	155/529 (29%)
	Female	35/41 (85%)	35/51 (67%)	32/42 (76%)	25/35 (74%)	5/7 (71%)	1/3 (33%)	333/529 (63%)
心动过速	<b>TACHYCARDIA</b>	26/2313 (1%)	33/5129 (1%)	28/2483 (1%)	22/3523 (1%)	21/787 (2%)	11/621 (2%)	54/7213 (1%)
	Male	16/26 (62%)	10/33 (30%)	8/28 (28%)	12/22 (55%)	10/21 (52%)	5/11 (45%)	22/54 (41%)
	Female	10/26 (38%)	22/33 (66%)	20/28 (72%)	10/22 (45%)	8/21 (35%)	5/11 (45%)	25/54 (46%)
视力模糊	<b>VISION BLURRED</b>	51/2313 (2%)	222/5129 (4%)	52/2483 (1%)	75/3523 (2%)	20/787 (2%)	19/621 (3%)	68/7213 (1%)
	Male	15/51 (29%)	56/222 (25%)	16/52 (30%)	23/75 (31%)	6/20 (27%)	5/19 (25%)	20/68 (29%)
	Female	36/51 (71%)	156/222 (70%)	36/52 (70%)	51/75 (68%)	14/20 (73%)	12/19 (60%)	46/68 (68%)
便秘	<b>CONSTIPATION</b>	84/2313 (3%)	297/5129 (5%)	84/2483 (3%)	123/3523 (3%)	60/787 (7%)	24/621 (4%)	243/7213 (3%)
	Male	26/84 (31%)	79/297 (27%)	32/84 (38%)	43/123 (35%)	26/60 (45%)	9/24 (29%)	99/243 (41%)
	Female	58/84 (69%)	214/297 (72%)	50/84 (62%)	76/123 (62%)	33/60 (53%)	14/24 (60%)	142/243 (58%)
口干	<b>DRY MOUTH</b>	175/2313 (7%)	<b>500/5129 (9%)</b>	<b>152/2483 (6%)</b>	236/3523 (7%)	81/787 (10%)	<b>80/621 (10%)</b>	<b>162/7213 (2%)</b>
	Male	63/175 (36%)	145/500 (29%)	43/152 (28%)	78/236 (33%)	30/81 (35%)	29/80 (33%)	59/162 (36%)
	Female	110/175 (63%)	345/500 (69%)	107/152 (72%)	150/236 (64%)	51/81 (65%)	50/80 (63%)	49/162 (30%)
认知障碍	<b>COGNITIVE DISORDER</b>	27/2313 (0,004%)	34/5129 (0,006%)	15/2483 (0,006%)	25/3523 (0,007%)	5/787 (0,006%)	5/621 (0,008%)	15/7213 (0,002%)
	Male	4/27 (15%)	7/34 (21%)	7/15 (47%)	7/25 (40%)	2/5 (40%)	2/5 (40%)	7/15 (47%)
	Female	15/27 (55%)	15/34 (44%)	6/15 (53%)	15/25 (60%)	3/5 (60%)	3/5 (60%)	7/15 (47%)
尿潴留	<b>URINARY RETENTION</b>	112/2313 (4%)	<b>520/5129 (10%)</b>	<b>580/2483 (23%)</b>	1525/3523 (43%)	58/787 (8%)	<b>35/621 (5%)</b>	<b>805/7213 (10%)</b>
	Male	41/112 (37%)	246/520 (47%)	260/580 (45%)	1019/1525 (69%)	32/58 (55%)	23/35 (66%)	423/805 (52%)
	Female	62/112 (55%)	248/520 (48%)	297/580 (51%)	424/1525 (28%)	24/58 (41%)	12/35 (34%)	362/805 (45%)

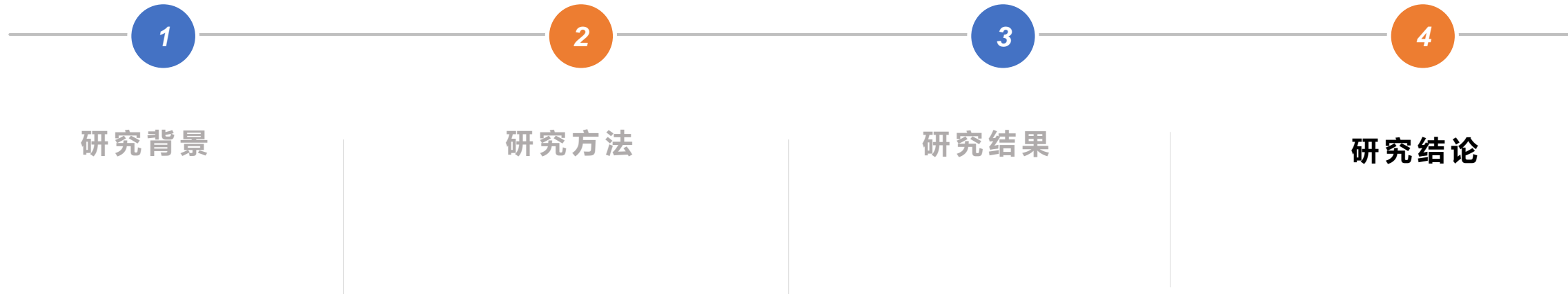
# 研究结果：尿潴留在高龄患者中的发生风险更高

	奥昔布宁	索利那新	托特罗定	非索罗定	曲司氯胺	丙哌维林	米拉贝隆	
高血压	HYPERTENSION	41/2313 (2%)	51/5129 (2%)	42/2483 (2%)	35/3523 (1%)	7/787 (1%)	3/621 (<1%)	529/7213 (7%)
	<65	20/41 (49%)	24/51 (49%)	11/42 (26%)	3/35 (9%)	0/7 (0%)	1/3 (33%)	126/529 (26%)
	65 - 85	20/41 (49%)	22/51 (41%)	24/42 (57%)	21/35 (60%)	4/7 (57%)	1/3 (33%)	366/529 (67%)
	>85	1/41 (2%)	5/51 (10%)	3/42 (7%)	2/35 (6%)	3/7 (43%)	1/3 (33%)	37/529 (7%)
心动过速	TACHYCARDIA	26/2313 (1%)	33/5129 (1%)	28/2483 (1%)	22/3523 (1%)	21/787 (2%)	11/621 (2%)	54/7213 (1%)
	<65	20/26 (77%)	19/33 (58%)	9/28 (32%)	6/22 (27%)	9/21 (46%)	6/11 (55%)	11/54 (21%)
	65-85	2/26 (8%)	11/33 (33%)	10/28 (36%)	10/22 (45%)	5/21 (25%)	2/11 (19%)	36/54 (66%)
	>85	4/26 (15%)	3/33 (9%)	3/28 (11%)	1/22 (5%)	2/21 (10%)	0/11 (0%)	7/54 (13%)
视力模糊	VISION BLURRED	51/2313 (2%)	222/5129 (4%)	52/2483 (1%)	75/3523 (2%)	20/787 (2%)	19/621 (3%)	68/7213 (1%)
	<65	12/51 (36%)	96/222 (47%)	13/52 (25%)	14/75 (19%)	9/20 (45%)	13/19 (65%)	28/68 (41%)
	65-85	18/51 (55%)	104/222 (48%)	23/52 (44%)	40/75 (53%)	9/20 (45%)	3/19 (15%)	34/68 (50%)
	>85	2/51 (4%)	12/222 (5%)	10/52 (19%)	8/75 (11%)	0/20 (0%)	0/19 (0%)	6/68 (9%)
便秘	CONSTIPATION	84/2313 (3%)	297/5129 (5%)	84/2483 (3%)	123/3523 (3%)	60/787 (7%)	24/621 (4%)	243/7213 (3%)
	<65	40/84 (48%)	76/297 (24%)	12/84 (14%)	18/123 (15%)	11/60 (19%)	3/24 (14%)	88/243 (36%)
	65-85	37/84 (44%)	178/297 (61%)	41/84 (49%)	69/123 (56%)	22/60 (38%)	12/24 (50%)	133/243 (55%)
	>85	7/84 (8%)	43/297 (15%)	14/84 (17%)	15/123 (12%)	7/60 (12%)	7/24 (30%)	22/243 (9%)
口干	DRY MOUTH	175/2313 (7%)	500/5129 (9%)	152/2483 (6%)	236/3523 (7%)	81/787 (10%)	81/621 (10%)	162/7213 (2%)
	<65	89/175 (49%)	207/500 (43%)	34/152 (22%)	50/236 (21%)	19/81 (23%)	6/81 (8%)	57/162 (33%)
	65-85	79/175 (47%)	265/500 (51%)	74/152 (49%)	121/236 (51%)	38/81 (45%)	42/81 (51%)	89/162 (57%)
	>85	7/175 (4%)	28/500 (6%)	23/152 (15%)	26/236 (10%)	8/81 (10%)	16/81 (20%)	16/162 (10%)
认知障碍	COGNITIVE DISORDER	27/2313 (0.004%)	34/5129 (0.006%)	15/2483 (0.006%)	25/3523 (0.007%)	5/787 (0.006%)	5/621 (0.008%)	15/7213 (0.002%)
	<65	15/27 (43%)	16/34 (47%)	0/15 (0%)	5/25 (20%)	0/5 (0%)	0/5 (0%)	7/15 (51%)
	65-85	10/27 (40%)	17/34 (50%)	4/15 (26%)	10/25 (40%)	3/5 (60%)	3/5 (60%)	6/15 (36%)
	>85	2/27 (7%)	1/34 (3%)	3/15 (20%)	6/25 (24%)	2/5 (40%)	2/5 (40%)	2/15 (13%)
尿潴留	URINARY RETENTION	112/2313 (4%)	520/5129 (10%)	580/2483 (23%)	1525/3523 (43%)	58/787 (8%)	35/621 (5%)	805/7213 (10%)
	<65	53/112 (49%)	214/520 (40%)	143/580 (25%)	109/1525 (7%)	7/58 (13%)	7/35 (21%)	88/805 (10%)
	65-85	46/112 (47%)	230/520 (45%)	265/580 (47%)	686/1525 (45%)	32/58 (59%)	18/35 (54%)	606/805 (75%)
	Age >85	13/112 (12%)	76/520 (15%)	67/580 (12%)	223/1525 (15%)	8/58 (15%)	6/35 (18%)	111/805 (15%)

- 对于年龄较大的患者(>85岁), 尿潴留在所有分析的药物中发生率较高;
- 其中奥昔布宁13/112(12%), 索利那新76/520(15%), 托特罗定67/580(12%), 非索罗定223/1525(15%), 曲司氯胺8/58(15%), 丙哌维林6/35(18%), 米拉贝隆111/805(15%)。



## - 文献重点内容 -



## 研究结论

与男性患者相比，女性患者有更高的AEs发生率。尿潴留在高龄患者（≥85岁）中的发生风险更高。

与竞品索利那新、托特罗定、非索罗定、曲司氯胺和米拉贝隆相比，**丙哌维林的高血压和尿潴留的发生率更低。**





**谢谢关注！**  
thanks for your attention.

